M 100 Series – General Applicability

Basis and Purpose – M 101

The statutory authority for this rule includes but is not limited to sections 12-43.3-102(2), 12-43.3-202(1)(b)(I), and 12-43.3-901(2), C.R.S. Unless such activity is authorized by the Colorado Constitution, article XVIII, Section 14 or Section 16, the Medical Marijuana Code, section 25-1.5-106.6, C.R.S., or these rules, any Person who buys, Transfers, or acquires Medical Marijuana is engaging in illegal activity pursuant to Colorado law. This rule clarifies that those engaged in the business of possessing, cultivating, dispensing, Transferring, transporting, or testing Medical Marijuana must be properly licensed to be in compliance with Colorado law.

M 101 – Engaging in Business

Except as authorized by the Colorado Constitution, article XVIII, sections 14 or 16, the Medical Marijuana Code, or section 25-1.5-106.5, C.R.S., no person shall, possess, cultivate, dispense, Transfer, transport, or offer to sell, manufacture, test, or research Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product unless said Person is duly licensed by the State Licensing Authority and the relevant local licensing authority(-ies).

Basis and Purpose – M 103

The statutory authority for this rule includes but is not limited to sections 12-43.3-104, 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a), 12-43.3-202(2)(a)(XX), C.R.S. , and all of the Medical Code. The purpose of this rule is to provide necessary definitions of terms used throughout the rules. Defined terms are capitalized where they appear in the rules, to let the reader know to refer back to these definitions. When a term is used in a conventional sense, and not intended to be a defined term, it is not capitalized.

M 103 – Definitions

Definitions. The following definitions of terms, in addition to those set forth in section 12-43.3-104, C.R.S., shall apply to all rules promulgated pursuant to the Medical Code, unless the context requires otherwise:

> "Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation, of visual, oral, or written communication, to induce directly or indirectly any Person to patronize a particular Medical Marijuana Business, or to purchase particular Medical Marijuana or a Medical Marijuana-Infused Product. "Advertising" includes marketing, but does not include packaging and labeling. "Advertising" proposes a commercial transaction or otherwise constitutes commercial speech.
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> "Affiliated Interest" means any Business Interest related to a Medical Marijuana Business that does not rise to the level of a Financial Interest in a Medical Marijuana Business license. An Affiliated Interest may include, but shall not be limited to, an Indirect Beneficial Interest Owner that is not a Financial Interest, an indirect financial interest, a lease agreement, secured or unsecured loan, or security interest in fixtures or equipment with a direct nexus to the cultivation, manufacture, Transfer, transportation, or testing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. A Person who provides funding for a Research Project conducted by a Licensed Research Business is an Affiliated Interest for the Licensed Research Business, unless that Person is a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner. Except as otherwise provided by these rules, an Affiliated Interest holder shall neither exercise control of nor be positioned so as to enable the exercise of control over the Medical Marijuana Business or its operations. A Medical Marijuana Business shall report each of its Affiliated Interests to the Division with each application for initial licensure, renewal, change of ownership or change of corporate structure.

"Agreement" means any unsecured convertible debt option, option agreement, warrant, or at the Division's discretion, other document that establishes a right for a person to obtain a Permitted Economic Interest that might convert to an ownership interest in a Retail Marijuana Establishment or Medical Marijuana Business.

"Alarm Installation Company" means a Person engaged in the business of selling, providing, maintaining, servicing, repairing, altering, replacing, moving or installing a Security Alarm System in a Licensed Premises.

"Applicant" means a Person that has submitted an application for licensure or registration, or for renewal of licensure or registration, pursuant to these rules that was accepted by the Division for review but has not been approved or denied by the State Licensing Authority.

"Associated Key License" means an Occupational License for an individual who is a Direct Beneficial Interest Owner of the Medical Marijuana Business, other than a Qualified Limited Passive Investor, and any Person who controls or is positioned so as to enable the exercise of control over a Medical Marijuana Business. Each shareholder, officer, director, member, or partner of a Closely Held Business Entity that is a Direct Beneficial Interest Owner and any Person who controls or is positioned as to enable the exercise of control over a Medical Marijuana Business must hold an Associated Key License.

"Batch Number" means any distinct group of numbers, letters, or symbols, or any combination thereof, assigned by a Medical Marijuana Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer to a specific Harvest Batch or Production Batch of Medical Marijuana.

"Business Interest" means any Person that holds a Financial Interest or an Affiliated Interest in a Medical Marijuana Business.

"Child-Resistant" means special packaging that is:

a. Designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995). Note that this rule does not include any later amendments or editions to the Code of Federal Regulations. The Division has maintained a copy of the applicable federal regulations, which is available to the public;

b. Opaque so that the packaging does not allow the product to be seen without opening the packaging material; and

c. Resealable for any product intended for more than a single use or containing multiple servings.

"Closely Held Business Entity" means an "entity" as defined in section 7-90-102, C.R.S., that has no more than fifteen shareholders, officers, directors, members, partners or owners, each of whom are natural persons, each of whom holds an Associated Key License, and each of whom is a United States citizen prior to the date of application. There must be no publicly traded market for interests in the entity. A Closely Held Business Entity and each of the natural persons who are its shareholders, officers, directors, members, partners or owners, are Direct Beneficial Interest Owners. A Closely Held Business Entity is an associated business of the Medical Marijuana Business for which it is a Direct Beneficial Interest Owner.

"Commercially Reasonable Royalty" means a right to compensation in the form of a royalty payment for the use of intellectual property with a direct nexus to the cultivation, manufacture,

Transfer, or testing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. A Commercially Reasonable Royalty must be limited to specific intellectual property the Commercially Reasonable Royalty Interest Holder owns or is otherwise authorized to license or to a product or line of products. A Commercially Reasonable Royalty will not be approved where it could cause reasonable consumer confusion or violate any federal copyright, trademark, or patent law or regulation. The Commercially Reasonable Royalty shall provide for compensation to the Commercially Reasonable Royalty Holder as a percentage of gross revenue or gross profit. The royalty payment must be at a reasonable percentage rate. To determine whether the percentage rate is reasonable, the Division will consider the totality of the circumstances, including but not limited to the following factors:

a. The percentage of royalties received by the recipient for the licensing of the intellectual property.

b. The rates paid by the Licensee for the use of other intellectual property.

c. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the product may be sold.

d. The licensor's established policy and marketing program to maintain his intellectual property monopoly by not licensing others or by granting licenses under special conditions designed to preserve that monopoly.

e. The commercial relationship between the recipient and Licensee, such as, whether they are competitors in the same territory in the same line of business.

f. The effect of selling the intellectual property in promoting sales of other products of the Licensee; the existing value of the intellectual property to the recipient as a generator of sales of his non-intellectual property items; and the extent of such derivative sales.

g. The duration of the term of the license for use of the intellectual property.

h. The established or projected profitability of the product made using the intellectual property; its commercial success; and its current popularity.

i. The utility and advantages of the intellectual property over products or businesses without the intellectual property.

j. The nature of the intellectual property; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the intellectual property.

k. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the intellectual property.

l. The portion of the realizable profit that should be credited to the intellectual property as distinguished from non-intellectual property elements, the manufacturing process, business risks, or significant features or improvements added by the Licensee.

"Commercially Reasonable Royalty Interest Holder" means a Person that receives a Commercially Reasonable Royalty in exchange for a Licensee's use of the Commercially

Reasonable Royalty Interest Holder's intellectual property. A Commercially Reasonable Royalty Interest Holder is an Indirect Beneficial Interest Owner.

"Container" means the receptacle directly containing Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that is labeled according to the requirements in Rules M 1001 *et. seq.* or Rules M 1001-1 *et seq.*

"Denied Applicant" means any Person whose application for licensure pursuant to the Medical Code has been denied.

"Department" means the Colorado Department of Revenue.

"Direct Beneficial Interest Owner" means a natural person or a Closely Held Business entity that owns a share or shares of stock in a licensed Medical Marijuana Business, including the officers, directors, members, or partners of the licensed Medical Marijuana Business or Closely Held Business Entity, or a Qualified Limited Passive Investor. Each natural person that is a Direct Beneficial Interest Owner must hold an Associated Key License. Except that a Qualified Limited Passive Investor need not hold an Associated Key License and shall not engage in activities for which an Occupational License is required.

"Director" means the Director of the Marijuana Enforcement Division.

"Division" means the Marijuana Enforcement Division.

"Edible Medical Marijuana-Infused Product" means any Medical Marijuana-Infused Product for which the intended use is oral consumption, including but not limited to, any type of food, drink, or pill.

"Executive Director" means the Executive Director of the Department of Revenue.

"Exit Package" means an Opaque bag or other similar Opaque covering provided at the point of sale, in which Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product already in a Container is placed. If Medical Marijuana flower, trim, or seeds are placed into a Container that is not Child-Resistant, then the Exit Package must be Child-Resistant.

"Final Agency Order" means an Order of the State Licensing Authority issued in accordance with the Medical Code and the State Administrative Procedure Act. The State Licensing Authority will issue a Final Agency Order following review of the Initial Decision and any exceptions filed thereto or at the conclusion of the declaratory order process. A Final Agency Order is subject to judicial review.

"Financial Interest" means any Direct Beneficial Interest Owner, a Commercially Reasonable Royalty Interest Holder who receives more than 30 percent of the gross revenue or gross profit, a Permitted Economic Interest holder, and any other Person who controls or is positioned so as to enable the exercise of control over the Medical Marijuana Business.

"Finished Marijuana" means post-harvest Medical Marijuana including flower and trim that has been harvested for more than 90 days or that has completed the curing and drying process according to the Optional Premises Cultivation Operation's written standard operating procedures that were last submitted to the Division. Standard operating procedures for curing and drying may provide a curing and drying period that is longer than 90 days but any such period must be commercially reasonable and shall not exceed 12 months. Among other factors, the Division may consider the Optional Premises Cultivation Operation's prior business years' business transactions to determine whether the Optional Premises Cultivation Operation's standard operating procedures are commercially reasonable.

“Flammable Solvent” means a liquid that has a flash point below 100 degrees Fahrenheit.

“Flowering” means the reproductive state of the Cannabis plant in which there are physicial signs of flower or budding out of the nodes in the stem.

“Food-Based Medical Marijuana Concentrate” means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of propylene glycol, glycerin, butter, olive oil or other typical cooking fats.

“Good Cause” for purposes of denial of an initial, renewal or reinstatement license application or certification, or for purposes of discipline of a license or certification, means:

a. The Licensee or Applicant has violated, does not meet, or has failed to comply with any of the terms, conditions, or provisions of the Medical Code, any rules promulgated pursuant it, or any supplemental relevant state or local law, rule, or regulation;

b. The Licensee or Applicant has failed to comply with any special terms or conditions that were placed upon the license pursuant to an order of the State Licensing Authority or the relevant local licensing authority; or

c. The Licensee’s or the Applicant’s Licensed Premises have been operated in a manner that adversely affects the public health or welfare or the safety of the immediate neighborhood in which the establishment is located.

“Good Moral Character” means having a personal history that demonstrates honesty, fairness, and respect for the rights of others and for the law.

“Harvest Batch” means a specifically identified quantity of processed Medical Marijuana that is uniform in strain, cultivated utilizing the same Pesticide and other agricultural chemicals and harvested at the same time.

“Heat/Pressure-Based Medical Marijuana Concentrate” means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of heat and/or pressure. The method of extraction may be used by only a Medical Marijuana-infused Products Manufacturer and can be used alone or on a Production Batch that also includes Water-Based Medical Marijuana Concentrate or Solvent-Based Medical Marijuana Concentrate.

“Identity Statement” means the name of the business as it is commonly known and used in any Advertising.

“Immature plant” means a nonflowering Medical Marijuana plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping or seedling and that is in a growing container that is no larger than two inches wide and two inches tall that is sealed on the sides and bottom. Plants meeting these requirements are not attributable to a Licensee’s maximum allowable plant count, but must be fully accounted for in the Inventory Tracking System.

“Indirect Beneficial Interest Owner” means a holder of a Permitted Economic Interest, a recipient of a Commercially Reasonable Royalty associated with the use of intellectual property by a Licensee, a Profit-Sharing Plan Employee, a Qualified Institutional Investor, or another similarly situated Person as determined by the State Licensing Authority. An Indirect Beneficial Interest Owner is not a Licensee. The Licensee must obtain Division approval for an Indirect Beneficial Interest Owner that constitutes a Financial Interest before such Indirect Beneficial Interest Owner may exercise any of the privileges of the ownership or interest with respect to the Licensee.

“Industrial Hemp” means a plant of the genus Cannabis and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry weight basis.

“Industrial Hygienist” means an individual who has obtained a baccalaureate or graduate degree in industrial hygiene, biology, chemistry, engineering, physics, or a closely related physical or biological science from and accredited college or university.

a. The special studies and training of such individuals shall be sufficient in the cognate sciences to provide the ability and competency to:

    1. Anticipate and recognize the environmental factors and stresses associated with work and work operations and to understand their effects on individuals and their well-being;

    2. Evaluate on the basis of training and experience and with the aid of quantitative measurement techniques the magnitude of such environmental factors and stresses in terms of their ability to impair human health and well-being;

    3. Prescribe methods to prevent, eliminate, control, or reduce such factors and stresses and their effects.

b. Any individual who has practiced within the scope of the meaning of industrial hygiene for a period of not less than five years immediately prior to July 1, 1997, is exempt from the degree requirements set forth in the definition above.

c. Any individual who has a two-year associate of applied science degree in environmental science from an accredited college or university and in addition not less than four years practice immediately prior to July 1, 1997, within the scope of the meaning of industrial hygiene is exempt from the degree requirements set forth in the definition above.

“Initial Decision” means a decision of a hearing officer in the Department following a licensing, disciplinary, or other administrative hearing.

“Inventory Tracking System” means the required seed-to-sale tracking system that tracks Medical Marijuana from either the seed or immature plant stage until the Medical Marijuana or Medical Marijuana Infused-Product is sold to a patient at a Medical Marijuana Center, Transferred to a Medical Research Facility, Transferred to a Pesticide Manufacturer, destroyed by a Medical Marijuana Business or used in a Research Project by a Licensed Research Business.

“Inventory Tracking System Trained Administrator” means an Associated Key Licensee of a Medical Marijuana Business or an occupationally licensed employee of a Medical Marijuana Business, each of whom has attended and successfully completed Inventory Tracking System training and has completed any additional training required by the Division.

“Inventory Tracking System User” means an Associated Key Licensee of a Medical Marijuana Business or an occupationally licensed Medical Marijuana Business employee who is granted Inventory Tracking System User account access for the purposes of conducting inventory tracking functions in the Inventory Tracking System. Each Inventory Tracking System Usermust have been successfully trained by Inventory Tracking System Trained Administrator(s) in the proper and lawful use Inventory Tracking System, and who has completed any additional training required by the Division.

"Key License" means an Occupational License for an individual who performs duties that are central to the Medical Marijuana Business' operation. An individual holding a Key License has the highest level of responsibility. An example of a Key Licensee includes, but is not limited to, managers.

"Licensed Premises" means the premises specified in an application for a license pursuant to the Medical Code that are owned or in possession of the Licensee and within which the Licensee is authorized to cultivate, manufacture, distribute, sell, store, transport, test, or research Medical Marijuana in accordance with the provisions of the Medical Code and these rules.

"Licensed Research Business" means a Marijuana Research and Development Facility or a Marijuana Research and Development Cultivation.

"Licensee" means any Person licensed or registered pursuant to the Medical Code, including an Occupational Licensee.

"Limited Access Area" means a building, room, or other contiguous area upon the Licensed Premises where Medical Marijuana is grown, cultivated, stored, weighed, packaged, Transferred, or processed for Transfer, under control of the Licensee.

"Limit of Detection" or "LOD" means the lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit (generally 1%).

"Limit of Quantitation" or "LOQ" means the lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

"Liquid Edible Medical Marijuana-Infused Product" means an Edible Medical Marijuana-Infused Product that is a liquid beverage or liquid food-based product for which the intended use is oral consumption, such as a soft drink or cooking sauce.

"Marijuana-Based Workforce Development Training Program" means a program designed to train individuals to work in the legal Medical or Retail Marijuana industry operated by an entity licensed under the Medical Code and/or the Retail Code or by a school that is authorized by the Division of Private Occupational Schools.

"Marketing Layer" means that packaging in addition to the Container that is the outermost layer visible to the consumer at the point of sale. The Marketing Layer is optional, but if used by a Licensee in addition to the required Container, it must be labeled according to the requirements in Rules M 1001 *et. seq.* or Rules M 1001-1 *et. seq.*

"Marijuana Research and Development Cultivation" means a Person that is licensed pursuant to the Medical Code to grow, cultivate, and possess Medical Marijuana, and to Transfer Medical Marijuana to a Medical Research and Development Facility or another Medical Research and Development Cultivation, all for limited research purposes authorized pursuant to section 12-43.3-408, C.R.S. A Marijuana Research and Development Cultivation is a Licensed Research Business.

"Marijuana Research and Development Facility" means a Person that is licensed pursuant to the Medical Code to possess Medical Marijuana for limited research purposes authorized pursuant to section 12-43.3-408, C.R.S. A Marijuana Research and Development Facility is a Licensed Research Business.

"Material Change" means any change that would require a substantive revision to a Medical Marijuana Business's standard operating procedures for the cultivation of Medical Marijuana or the production of a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

"Medical Code" means the Colorado Medical Marijuana Code found at sections 12-43.3-101 *et. seq.*, C.R.S.

"Medical Marijuana" means marijuana that is grown and sold pursuant to the Medical Code and includes seeds and Immature Plants. Unless the context otherwise requires, Medical Marijuana Concentrate is considered Medical Marijuana and is included in the term Medical Marijuana as used in these rules.

"Medical Marijuana Business" means a licensed Medical Marijuana Center, a Medical Marijuana-Infused Products Manufacturer, an Optional Premises Cultivation Operation, a Medical Marijuana Testing Facility, a Medical Marijuana Business Operator, a Medical Marijuana Transporter, a Marijuana Research and Development Facility, or a Marijuana Research and Development Cultivation.

"Medical Marijuana Business Operator" means an entity that holds a registration or license from the State Licensing Authority to provide professional operational services to one or more Medical Marijuana Businesses, other than Licensed Research Businesses, for direct remuneration from the Medical Marijuana Business(es), which may include compensation based upon a percentage of the profits of the Medical Marijuana Business(es) being operated. A Medical Marijuana Business Operator may contract with Medical Marijuana Business(es) to provide operational services. A Medical Marijuana Business Operator's contract with a Medical Marijuana Business does not in and of itself constitute ownership. The Medical Code and rules apply to all Medical Marijuana Business Operators regardless of whether such operator holds a registration or license. Any reference to "license" or "licensee" shall mean "registration" or "registrant" when applied to a Medical Marijuana Business Operator that holds a registration issued by the State Licensing Authority.

"Medical Marijuana Center" means a Person that is licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-402, C.R.S., and that sells Medical Marijuana to registered patients or primary caregivers as defined in Article XVIII, Section 14 of the Colorado Constitution, but is not a primary caregiver.

"Medical Marijuana Concentrate" means a specific subset of Medical Marijuana that was produced by extracting Cannabinoids from Medical Marijuana. Categories of Medical Marijuana Concentrate include Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, Solvent-Based Medical Marijuana Concentrate, and Heat/Pressure-Based Medical Marijuana Concentrate.

"Medical Marijuana-Infused Product" means a product infused with Medical Marijuana that is intended for use or consumption other than by smoking, including but not limited to edible products, ointments, and tinctures. Such products shall not be considered a food or drug for purposes of the "Colorado Food and Drug Act," part 4 of Article 5 of Title 25, C.R.S.

"Medical Marijuana-Infused Products Manufacturer" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-404, C.R.S.

"Medical Marijuana Testing Facility" means a public or private laboratory licensed and certified, or approved by the Division, to conduct testing and research on Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product.

“Medical Marijuana Transporter” means a Person that is licensed to transport Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product from one Medical Marijuana Business to another Medical Marijuana Business or to a Medical Research Facility or Pesticide Manufacturer, and to temporarily store the transported Medical Marijuana and Medical Marijuana-Infused Product at its licensed premises, but is not authorized to sell, give away, buy, or receive complimentary Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product under any circumstances. A Medical Marijuana Transporter does not include a Licensee that transports its own Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

“Medical Research Facility” means a Person approved and grant-funded by the State Board of Health pursuant to section 25-1.5-106.5, C.R.S., to conduct Medical Marijuana research. A Medical Marijuana Research Facility is neither a Medical Marijuana Business, a Retail Marijuana Establishment, nor a Licensee.

“Monitoring” means the continuous and uninterrupted attention to potential alarm signals that could be transmitted from a Security Alarm System located at a Medical Marijuana Business Licensed Premises, for the purpose of summoning a law enforcement officer to the premises during alarm conditions.

“Monitoring Company” means a Person in the business of providing Monitoring services for a Medical Marijuana Business.

“Notice of Denial” means a written statement from the State Licensing Authority, articulating the reasons or basis for denial of a license application.

“Occupational License” means a license granted to an individual by the State Licensing Authority pursuant to section 12-43.3-401, C.R.S. An Occupational License may be an Associated Key License, a Key License or a Support License.

“Opaque” means that the packaging does not allow the product to be seen without opening the packaging material.

“Optional Premises Cultivation Operation” means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-403, C.R.S.

“Order to Show Cause” means a document from the State Licensing Authority alleging the grounds for imposing discipline against a Licensee’s license.

“Owner” means, except where the context otherwise requires, a Direct Beneficial Interest Owner.

“Permitted Economic Interest” means an Agreement to obtain an ownership interest in a Retail Marijuana Establishment or Medical Marijuana Business when the holder of such interest is a natural person who is a lawful United States resident and whose right to convert into an ownership interest is contingent on the holder qualifying and obtaining a license as a Direct Beneficial Interest Owner under the Retail Code or Medical Code. A Permitted Economic Interest holder is an Indirect Beneficial Interest Owner.

“Person” means a natural person, partnership, association, company, corporation, limited liability company, or organization, or a manager, agent, owner, director, servant, officer, or employee thereof; except that “Person” does not include any governmental organization.

“Pesticide” means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest or any substance or mixture of substances intended for use as a

plant regulator, defoliant or desiccant; except that the term “pesticide” shall not include any article that is a “new animal drug” as designated by the United States Food and Drug Administration.

“Pesticide Manufacturer” means a Person who: (1) manufactures, prepares, compounds, propagates, or processes any Pesticide or device or active ingredient used in producing a Pesticide; (2) who possesses an establishment number with the U.S. Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et. seq.;* (3) who conducts research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Medical Marijuana; (4) who has applied for and received any necessary license, registration, certifications, or permits from the Colorado Department of Agriculture pursuant to the Pesticide Act, section 35-9-101 *et. seq.*, C.R.S., and/or the Pesticide Applicators’ Act, sections 35-10-101 *et seq.*, C.R.S.; (5) who is authorized to conduct business in the State of Colorado; and (6) who has physical possession of the location in the State of Colorado where its research activities occur. A Pesticide Manufacturer is neither a Medical Marijuana Business, a Retail Marijuana Establishment, nor a Licensee.

“Production Batch” means (a) any amount of Medical Marijuana Concentrate of the same category and produced using the same extraction methods, standard operating procedures and an identical group of Harvest Batch(es) of Medical Marijuana; or (b) any amount of Medical Marijuana Product of the same exact type, produced using the same ingredients, standard operating procedures and the same Production Batch(es) of Medical Marijuana Concentrate.

“Professional Engineer” means an individual who is licensed by the State of Colorado as a professional engineer pursuant to 12-25-101 et. seq., C.R.S.

“Proficiency Testing” means an assessment of the performance of a Medical Marijuana Testing Facility’s methodology and processes. Proficiency Testing is also known as inter-laboratory comparison. The goal of Proficiency Testing is to ensure results are accurate, reproducible, and consistent.

“Profit-Sharing Plan” means a profit-sharing plan that is qualified pursuant to 26 U.S.C. § 401 of the Internal Revenue Code and subject to the Employee Retirement Income Security Act, and which provides for employer contributions in the form of cash, but not in the form of stock or other equity interests in a Medical Marijuana Business.

“Profit-Sharing Plan Employee” means an employee holding an Occupational License who receives a share of a Medical Marijuana Business’s profits through a Profit-Sharing Plan. A Profit-Sharing Plan Employee is an Indirect Beneficial Interest Owner.

“Propagation” means the reproduction of Medical Marijuana plants by seeds, cuttings or grafting.

“Public Institution” means any entity established or controlled by the federal government, a state government, or a local government or municipality, including but not limited to institutions of higher education or public higher education research institutions.

“Public Money” mean any funds or money obtained by the holder from any governmental entity, including but not limit to research grants.

“Qualified Institutional Investor” means:

a. A bank as defined in Section 3(a) (6) of the Federal Securities Exchange Act of 1934, as amended;

b. An insurance company as defined in Section 2(a) (17) of the Investment Company Act of 1940, as amended;

c. An investment company registered under Section 8 of the Investment Company Act of 1940, as amended;

d. An investment adviser registered under Section 203 of the Investment Advisers Act of 1940, as amended;

e. Collective trust funds as defined in Section 3(c) (11) of the Investment Company Act of 1940, as amended;

f. An employee benefit plan or pension fund that is subject to the Employee Retirement Income Security Act of 1974, as amended, excluding an employee benefit plan or pension fund sponsored by a licensed or an intermediary or holding company licensee which directly or indirectly owns five percent or more of a licensee;

g. A state or federal government pension plan; or

h. A group comprised entirely of persons specified in (a) through (g) of this definition.

A Qualified Institutional Investor is an Indirect Beneficial Interest Owner.

"Qualified Limited Passive Investor" means a natural person who is a United States citizen and is a passive investor who owns less than a five percent share or shares of stock in a licensed Medical Marijuana Business. A Qualified Limited Passive Investor is a Direct Beneficial Interest Owner.

"RFID" means Radio Frequency Identification.

"Remediation" means the process by which Medical Marijuana flower or trim, which has failed microbial testing, is processed into Solvent-Based Medical Marijuana Concentrate and retested as required by these rules.

"Resealable" means that the Container maintains its Child-Resistant effectiveness for multiple openings.

"Research Project" means a discrete scientific endeavor to answer a research question or a set of research questions. A Research Project must include a description of a defined protocol, clearly articulated goal(s), defined methods and outputs, and a defined start and end date. The description must demonstrate that the Research Project will comply with all requirements in the M 1900 Series. All research and development conducted by a Licensed Research Business must be conducted in furtherance of an approved Research Project.

"Respondent" means a person who has filed a petition for declaratory order that the State Licensing Authority has determined needs a hearing or legal argument or a Licensee who is subject to an Order to Show Cause.

"Restricted Access Area" means a designated and secure area within a Licensed Premises in a Medical Marijuana Center where Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product are sold, possessed for sale, and displayed for sale, and where no one without a valid patient registry card is permitted.

"Retail Code" means the Colorado Retail Marijuana Code, found at sections 12-43.4-101 *et. seq*, C.R.S.

“Retail Marijuana” means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including but not limited to Retail Marijuana Concentrate that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Establishment. “Retail Marijuana” does not include industrial hemp, nor does it include fiber produced from stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product. Unless the context otherwise requires, Retail Marijuana Concentrate is considered Retail Marijuana and is included in the term “Retail Marijuana” as used in these rules.

“Retail Marijuana Concentrate” means a specific subset of Retail Marijuana that was produced by extracting Cannabinoids from Retail Marijuana. Categories of Retail Marijuana Concentrate include Water-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate, Solvent-Based Retail Marijuana Concentrate, and Heat/Pressure-Based Retail Marijuana Concentrate.

“Retail Marijuana Cultivation Facility” means an entity licensed to cultivate, prepare, and package Retail Marijuana and Transfer Retail Marijuana to Retail Marijuana Establishments, Medical Research Facilities, and Pesticide Manufacturers, but not to consumers.

“Retail Marijuana Establishment” means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturing Facility, a Retail Marijuana Testing Facility, a Retail Marijuana Establishment Operator, or a Retail Marijuana Transporter.

“Retail Marijuana Establishment Operator” means an entity that holds a license from the State Licensing Authority to provide professional operational services to one or more Retail Marijuana Establishments for direct remuneration from the Retail Marijuana Establishment(s), which may include compensation based upon a percentage of the profits of the Retail Marijuana Establishment(s) being operated. A Retail Marijuana Establishment Operator contracts with Retail Marijuana Establishment(s) to provide operational services. A Retail Marijuana Establishment Operator’s contract with a Retail Marijuana Establishment does not in and of itself constitute ownership.

“Retail Marijuana Product” means a product that is comprised of Retail Marijuana and other ingredients and is intended for use or consumption, such as, but not limited to, edible product, ointments and tinctures.

“Retail Marijuana Products Manufacturing Facility” means an entity licensed to purchase Retail Marijuana; manufacture, prepare, and package Retail Marijuana Product; and Transfer Retail Marijuana and Retail Marijuana Product to other Retail Marijuana Products Manufacturing Facilities,Retail Marijuana Stores, Medical Research Facilities, and Pesticide Manufacturers, but not to consumers.

“Retail Marijuana Store” means an entity licensed to purchase Retail Marijuana from a Retail Marijuana Cultivation Facility and to purchase Retail Marijuana Product from a Retail Marijuana Products Manufacturing Facility and to Transfer Retail Marijuana and Retail Marijuana Product to consumers.

“Retail Marijuana Testing Facility” means a public or private laboratory licensed and certified, or approved by the Division, to conduct testing and research on Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Products.

“Retail Marijuana Transporter” means a Person that is licensed to transport Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Products from one Retail Marijuana

Establishment to another Retail Marijuana Establishment or to a Medical Research Facility or Pesticide Manufacturer, and to temporarily store the transported Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Products at its Licensed Premises, but is not authorized to sell, give away, buy, or receive complimentary Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Products under any circumstances. A Retail Marijuana Transporter does not include a Licensee that transports and distributes its own Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Products.

"Sample" means any item collected from a Medical Marijuana Business and provided to a Medical Marijuana Testing Facility for testing. The following is a non-exhaustive list of types of Samples: Medical Marijuana, Medical Marijuana-Infused Product, Medical Marijuana Concentrate, soil, growing medium, water, solvent or swab of a counter or equipment.

"Security Alarm System" means a device or series of devices, intended to summon law enforcement personnel during, or as a result of, an alarm condition. Devices may include hard-wired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audible, visual, or electronic signal; motion detectors, pressure switches, duress alarms (a silent system signal generated by the entry of a designated code into the arming station to indicate that the user is disarming under duress); panic alarms (an audible system signal to indicate an emergency situation); and hold-up alarms (a silent system signal to indicate that a robbery is in progress).

"Shipping Container" means a hard-sided container with a lid or other enclosure that can be secured in place. A Shipping Container is used solely for the transport of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product between Medical Marijuana Businesses, a Medical Research Facility, or a Pesticide Manufacturer.

"Solvent-Based Medical Marijuana Concentrate" means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of a solvent approved by the Division pursuant to Rule M 605.

"Standardized Graphic Symbol" means a graphic image or small design adopted by a Licensee to identify its business.

"State Licensing Authority" means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacture, distribution, and Transfer of Medical Marijuana and Retail Marijuana in Colorado, pursuant to section 12-43.3-201, C.R.S.

"Support License" means a license for an individual who performs duties that support the Medical Marijuana Business' operations. A Support Licensee is a Person with less decision-making authority than a Key Licensee and who is reasonably supervised by a Key Licensee or an Associated Key Licensee. Examples of individuals who need this type of license include, but are not limited to, sales clerks or cooks.

"THC" means tetrahydrocannabinol.

"THCA" means tetrahydrocannabinolic acid.

"Test Batch" means a group of Samples that are derived from a single Harvest Batch, Production Batch, or Inventory Tracking System package, and that are collectively submitted to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility for testing purposes. "Total THC" means the sum of the percentage by weight of THCA multiplied by 0.877 plus the percentage by weight of THC, i.e., Total THC = (% THCA x 0.877) + % THC.

"Transfer(s)(ed)(ing)" means to grant, convey, hand over, assign, sell, exchange, donate, or barter, in any manner or by any means, with or without consideration, any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from one Licensee to another Licensee or to a patient. A Transfer includes the movement of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from one Licensed Premises to another, even if both premises are contiguous, and even if both premises are owned by a single entity or individual or group of individuals, and also includes a virtual Transfer that is reflected in the Inventory Tracking System, even if no physical movement of the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product occurs.

"Universal Symbol" means the image established by the Division and made available to Licensees through the Division's website indicating the Medical Marijuana or Medical Marijuana Infused-Product contains marijuana.

"Unrecognizable" means marijuana or *Cannabis* plant material rendered indistinguishable from any other plant material.

"Vegetative" means the state of the *Cannabis* plant during which plants do not produce resin or flowers and are bulking up to a desired production size for Flowering.

"Water-Based Medical Marijuana Concentrate" means a Medical Marijuana Concentrate that was produced by extracting cannabinoids from Medical Marijuana through the use of only water, ice, or dry ice.

M 200 Series – Licensing and Interests

Basis and Purpose – M 201

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-301(3), 12-43.3-401(1)(a)-(e), 12-43.3-104, 12-43.3-305, 12-43.3-306, 12-43.3-307.5, 12-43.3-310, 12-43.3-311, 12-43.3-313, 12-43.3-401, and 24-76.5-103, C.R.S. The purpose of this rule is to establish that only materially complete applications for licenses or registrations, accompanied by all required fees, will be accepted and processed by the Division. The purpose of this rule is also to clarify that when an initial application is materially complete, but the Division determines further information is required before the application can be fully processed, the Applicant must provide the additional requested information within the time frame provided by the Division. Otherwise, the Division cannot act on the application in a timely manner, and the application may be denied.

M 201 – Application Process

A. General Requirements

1. All applications for licenses or registrations authorized pursuant to subsections 12-43.3-401(1)(a)-(h), C.R.S., shall be made upon current forms prescribed by the Division.

2. A license or registration issued to a Medical Marijuana Business or an individual constitutes a revocable privilege. The burden of proving an Applicant's qualifications for licensure or registration rests at all times with the Applicant.

3. Each application shall identify the local licensing authority.

4. Applicants must submit a complete application to the Division before it will be accepted or considered.

a. All applications must be complete and accurate in every material detail.

b. All applications must include all attachments or supplemental information required by the current forms supplied by the Division.

c. All applications must be accompanied by a full remittance for the whole amount of the application and license fees. *See* Rule M 207 – Schedule of Application Fees: Medical Marijuana Businesses; Rule M 208 – Schedule of Business License and Registration Fees: Medical Marijuana Businesses; Rule M 209 – Schedule of Business Renewal License and Registration Fees: Medical Marijuana Businesses; Rule M 235 – Schedule of License Fees: Individuals; and Rule M 236 – Schedule of Renewal License Fees: Individuals.

d. All applications must include all information required by the Division related to the Applicant's proposed Direct Beneficial Interest Owners, Indirect Beneficial Interest Owners and Qualified Limited Passive Investors, and all other direct and indirect financial interests in the Applicant.

e. At a minimum, each Applicant for a new license or registration shall provide, at the time of application, the following information:

    i. For each Associated Key License Applicant, evidence of proof of lawful presence, citizenship, if applicable, residence, if applicable, and Good Moral Character as required by the current forms prescribed by the Division;

    ii. For each Medical Marijuana Business Applicant and each Associated Key License Applicant, all requested information concerning financial and management associations and interests of other Persons in the business;

    iii. If the Applicant for any license pursuant to the Medical Code is a Closely Held Business Entity it shall submit with the application:

        A. The Associated Key License applications for all of its shareholders, members, partners, officers and directors who do not already hold an Associated Key License;

        B. If the Closely Held Business Entity is a corporation, a copy of its articles of incorporation or articles of organization; evidence of authorization from the Colorado Secretary of State to do business within this State, and for each shareholder: his or her name, mailing address, state of residence and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business;

        C. If the Closely Held Business Entity is a limited liability company, a copy of its articles of organization and its operating agreement; evidence of authorization from the Colorado Secretary of State to do business within this State, and for each member: his or her name, mailing address, state of residence and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business; and

D. If the Closely Held Business Entity is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, a copy of the partnership agreement and, for each partner, his or her name, mailing address and state of residency and certification of Colorado residency for at least one officer and all officers with day-to-day operational control over the business.

iv. For each Medical Marijuana Business Applicant and each Associated Key License Applicant, documentation establishing compliant return filing and payment of taxes related to any Medical Marijuana Business or Retail Marijuana Establishment in which such Applicant is, or was, required to file and pay taxes;

v. For each Medical Marijuana Business Applicant and each Associated Key License Applicant, documentation verifying and confirming the funds used to start and/or sustain the operation of the Medical or Retail Marijuana Establishment were lawfully earned or obtained;

vi. Accurate floor plans for the premises to be licensed; and

vii. The deed, lease, sublease, contract, or other document(s) governing the terms and conditions of occupancy of the premises to be licensed.

5. All applications to reinstate a license or registration will be deemed an application for a new license or registration. This includes, but is not limited to, Associated Key licenses that have expired, Medical Marijuana Business licenses or registrations that have been expired for more than 90 days, licenses or registrations that have been voluntarily surrendered, and licenses that have been revoked.

6. The Division may refuse to accept an incomplete application.

B. Additional Information May Be Required

1. Upon request by the Division, an Applicant shall provide any additional information required to process and fully investigate the application. The additional information must be provided to the Division no later than seven days after the request is made unless otherwise specified by the Division.

2. An Applicant's failure to provide the requested information by the Division deadline may be grounds for denial of the application.

C. Information Must Be Provided Truthfully. All Applicants shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the Applicant made misstatements, omissions, misrepresentations, or untruths in the application or in connection with the Applicant's background investigation. This type of conduct may be considered as the basis for additional administrative action against the Applicant and it may also be the basis for criminal charges against the Applicant.

D. Application Forms Accessible. All application forms supplied by the Division and filed by an Applicant for a license, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Medical Code, the Retail Code, of for any other state or local law enforcement purpose or as otherwise required by law.

E. Division Application Management and Local Licensure.

1. Repealed.2. If the Division grants a license before the local licensing authority approves the application or grants a local license, the license will be conditioned upon local approval. Such condition will not be viewed as a denial pursuant to the Administrative Procedure Act. If the local licensing authority denies the application, the state license will be revoked.

3. An Applicant is prohibited from operating a Medical Marijuana Business prior to obtaining all necessary licenses, registrations or approvals from both the State Licensing Authority and the local licensing authority.

4. Each Financial Interest is void and of no effect unless and until approved by the Division. A Financial Interest shall not exercise any privilege associated with the proposed interest until approved by the Division. Any violation of this requirement may be considered a license or registration violation affecting public safety.

Basis and Purpose – M 202.1

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXI), and sections 12-43.3-104(1.7), 12-43.3-104(12.4), 12-43.3-305 and 12-43.3-306, 12-43.3-307.5, 12-43.3-310 and 12-43.3-313 C.R.S. The purpose of this rule is to clarify the process to be followed when a Medical Marijuana Business applies to obtain financing or otherwise have a relationship with an Indirect Beneficial Interest Owner. This rule establishes that only materially complete Medical Marijuana Business applications for Indirect Beneficial Interest Owners, accompanied by all required fees, will be accepted and processed by the Division. This rule also clarified that when an initial application is materially complete and accepted, but the Division determines further information is required before the application can be fully processed, the Medical Marijuana Business Applicant must provide the additional requested information within the time frame provided by the Division. Otherwise, the Division cannot act on the application in a timely manner and the Medical Marijuana Business' application may be denied. The rule also sets forth requirements for the contents of the contract or Agreement between Medical Marijuana Businesses and Indirect Beneficial Interest Owners, which reflect basic legal requirements surrounding the relationship between the parties.

M 202.1 – Applications, Agreements, Contracts and Certifications Required for Indirect Beneficial Interest Owners: Medical Marijuana Businesses

A. Medical Marijuana Business Initiates Process. The Medical Marijuana Business seeking to obtain financing or otherwise establish any type of relationship with an Indirect Beneficial Interest Owner, including a Permitted Economic Interest, a Commercially Reasonably Royalty Interest Holder, a Profit-Sharing Plan Employee, or a Qualified Institutional Investor, must file all required documents with the Division, including any supplemental documents requested by the Division in the course of its review of the application.

B. General Requirements. The Medical Marijuana Business seeking approval of an Indirect Beneficial Interest Owner must meet the following requirements:

1. All applications for approval of an Indirect Beneficial Interest Owner shall be made upon current forms prescribed by the Division.

2. The burden of proving that a proposed Indirect Beneficial Interest Owner is qualified to hold such an interest rests at all times with the Medical Marijuana Business submitting the application.

3. The Medical Marijuana Business applying for approval of any type of Indirect Beneficial Interest Owner must submit a complete application to the Division before it will be accepted or considered.

4. All applications must be complete and accurate in every material detail.

5. All applications must include all attachments or supplemental information required by the current forms supplied by the Division.

6. All applications must be accompanied by a full remittance of the required fees.

7. The Division may refuse to accept an incomplete application.

8. The proposed holder of the Indirect Beneficial Interest is not a publicly traded company.

9. Additional Information May Be Required

    a. Upon request by the Division, a Medical Marijuana Business applying to have any type of Indirect Beneficial Interest Owner shall provide any additional information required to process and fully investigate the application. The additional information must be provided to the Division no later than seven days after the request is made unless otherwise specified by the Division.

    b. Failure to provide the requested information by the Division's deadline may be grounds for denial of the application.

C. Information Must Be Provided Truthfully. A Medical Marijuana Business applying for approval of any type of Indirect Beneficial Interest Owner shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where any party made misstatements, omissions, misrepresentations, or untruths in the application or in connection with the background investigation of the proposed Indirect Beneficial Interest Owner. This type of conduct may be considered as the basis for additional administrative action against the Medical Marijuana Business and it may also be the basis for criminal charges against either the Medical Marijuana Business Applicant or the Indirect Beneficial Interest Owner.

D. Application Forms Accessible. All application forms supplied by the Division and filed by an Applicant for a license, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Medical Code, the Retail Code or for any other state or local law enforcement purpose, or as otherwise required by law.

E. Approval of Financial Interest. Each Financial Interest in a Medical Marijuana Business is void and of no effect unless and until approved by the Division. Any amendment of a Financial Interest is also void and of no effect unless and until approved by the Division.

F. Ongoing Qualification and Violation Affecting Public Safety. If at any time the Division finds any Indirect Beneficial Interest Owner is not qualified, or is no longer qualified, the Division may require the Medical Marijuana Business to terminate its relationship with and financial ties to the Indirect Beneficial Interest Owner within a specified time period. Failure to terminate such relationship and financial ties within the specified time period may constitute a violation affecting public safety and be a basis for administrative action against the Medical Marijuana Business.

G. Permitted Economic Interest Holder Requirements. At the time of application, a Medical Marijuana Business seeking to obtain approval of a Permitted Economic Interest shall provide evidence to establish that the natural person seeking to become a Permitted Economic Interest

holder is a lawful resident of the United States and shall provide documentation verifying and confirming the funds used for the Permitted Economic Interest were lawfully earned or obtained.

H. Permitted Economic Interest Agreement Requirements. The Medical Marijuana Business Applicant seeking to obtain financing from a Permitted Economic Interest must submit a copy of the Agreement between the Medical Marijuana Business and the person seeking to hold a Permitted Economic Interest. The following requirements apply to all Agreements:

1. The Agreement must be complete, and must fully incorporate all terms and conditions.

2. The following provisions must be included in the Agreement:

a. Any interest in a Medical Marijuana Business, whether held by a Permitted Economic Interest or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any Agreement or other interest in violation thereof shall be void. The Permitted Economic Interest holder shall not provide funding to the Medical Marijuana Business until the Permitted Economic Interest is approved by the Division.

b. No Agreement or other interest issued by the Medical Marijuana Business and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.

c. The Medical Marijuana Business and the Permitted Economic Interest holder must sign an affirmation of passive investment on a form approved by the Division.

d. The Medical Marijuana Business must initiate any process to convert a Permitted Economic Interest to a Direct Beneficial Interest Owner and the process to convert the Permitted Economic Interest into a Direct Beneficial Interest Owner must be completed prior to the expiration or termination of the Agreement. The holder of the Permitted Economic Interest must meet all qualifications for licensure and ownership pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder prior to conversion of the Permitted Economic Interest to a Direct Beneficial Interest Owner.

e. At the election of the Medical Marijuana Business, if the holder of the Permitted Economic Interest is not qualified for licensure as a Direct Beneficial Interest Owner but is qualified as a holder of the Permitted Economic Interest, and the Permitted Economic Interest is also approved by the Division then the Permitted Economic Interest may remain in force and effect for as long as it remains approved by the Division under the Medical Code and/or Retail Code as applicable, and any rules promulgated thereunder.

f. The Permitted Economic Interest holder shall disclose in writing to the Division and to the Medical Marijuana Business any and all disqualifying events, within ten days after occurrence of the event, that could lead to a finding that the holder no longer qualifies to hold the Permitted Economic Interest and/or that could lead to a denial of licensure pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder.

g. The Medical Marijuana Business shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which

could lead to a finding that the holder is no longer qualified to hold the Permitted Economic Interest and/or that could lead to a denial of licensure pursuant to the Medical Code and/or Retail Code as applicable, and any rules promulgated thereunder.

h. A Permitted Economic Interest holder's or a Medical Marijuana Business' failure to make required disclosures may be grounds for administrative action including but not limited to denial of a subsequent request to convert the Permitted Economic Interest into an ownership interest in the Medical Marijuana Business. Failure to make required disclosures may lead to a finding that the Permitted Economic Interest is no longer approved, and a requirement that the Medical Marijuana Business terminate its relationship with the Permitted Economic Interest holder.

i. The Permitted Economic Interest holder agrees and acknowledges that it has no entitlement or expectation of being able to invest in, or have a relationship with, the Medical Marijuana Business unless and until the Division determines the Permitted Economic Interest is approved. The Permitted Economic Interest holder agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval. The Permitted Economic Interest holder understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Permitted Economic Interest or find that the Permitted Economic Interest is no longer qualified. The Permitted Economic Interest Holder agrees and acknowledges it has no entitlement to or expectation of the Division approving the Permitted Economic Interest. The Permitted Economic Interest holder further agrees that any administrative or judicial review of a determination by the Division regarding the qualification or approval of the Permitted Economic Interest will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. The Permitted Economic Interest holder further agrees and acknowledges that the Permitted Economic Interest holder shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest holder. The Permitted Economic Interest holder also agrees and acknowledges that the Permitted Economic Interest holder may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest holder. Furthermore, the Permitted Economic Interest holder agrees and acknowledges that the Permitted Economic Interest holder may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Permitted Economic Interest Holder. THE PERMITTED ECONOMIC INTEREST HOLDER KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE PERMITTED ECONOMIC INTEREST BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE PERMITTED ECONOMIC INTEREST, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.

I. Commercially Reasonable Royalty Interest Contract Requirements. A Medical Marijuana Business seeking to utilize the intellectual property of a Commercially Reasonable Royalty Interest Holder must submit a copy of the contract between the Medical Marijuana Business and the Person seeking to hold a Commercially Reasonable Royalty Interest. The following requirements apply to all such contracts:

1. The contract must be complete, and must fully incorporate all terms and conditions.

2. The following provisions must be included in the contract:

   a. Any interest in a Medical Marijuana Business, whether held by a Commercially Reasonable Royalty Interest Holder or any other Person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any contract or other interest in violation thereof shall be void.

   b. No contract, royalty or other interest issued by the Medical Marijuana Business and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.

   c. The Medical Marijuana Business and the Commercially Reasonable Royalty Interest Holder must sign an affirmation of passive investment on a form approved by the Division.

   d. The Commercially Reasonable Royalty Interest Holder shall disclose in writing to the Division and to the Medical Marijuana Business any and all disqualifying events, within ten days after occurrence of the event, that could lead to a finding that the Commercially Reasonable Royalty Interest Holder is not qualified to hold the Commercially Reasonable Royalty Interest.

   e. The Medical Marijuana Business shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which would lead to a finding that the Commercially Reasonable Royalty Interest Holder is not qualified to hold the Commercially Reasonable Royalty Interest.

   f. A Commercially Reasonable Royalty Interest Holder's or a Medical Marijuana Business' failure to make required disclosures may lead to a finding that the Commercially Reasonable Royalty Interest is not approved, or is no longer approved, and may lead to a requirement that the Medical Marijuana Business terminate its relationship with the Commercially Reasonable Royalty Interest Holder.

   g. The Commercially Reasonable Royalty Interest Holder agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval throughout the entire term of its relationship with the Medical Marijuana Business. The Commercially Reasonable Royalty Interest Holder understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, find that the Commercially Reasonable Royalty Interest Holder does not qualify or no longer qualifies. The Commercially Reasonable Royalty Interest Holder agrees and acknowledges it has no entitlement to or expectation to approval of the Commercially Reasonable Royalty Interest.

h. The Commercially Reasonable Royalty Interest Holder further agrees that any administrative or judicial review of a determination by the Division approving or denying the Commercially Reasonable Royalty will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. The Commercially Reasonable Royalty Interest Holder further agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. The Commercially Reasonable Royalty Interest Holder also agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. Furthermore, the Commercially Reasonable Royalty Interest Holder agrees and acknowledges that the Commercially Reasonable Royalty Interest Holder may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Commercially Reasonable Royalty Interest Holder. THE COMMERCIALLY REASONABLE ROYALTY INTEREST HOLDER KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE COMMERCIALLY REASONABLE ROYALTY INTEREST BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE COMMERCIALLY REASONABLE ROYALTY INTEREST HOLDER, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.

i. If the Division determines the Commercially Reasonable Royalty Interest Holder is not in compliance with the Medical Code, the Retail Code, or these rules, then the recipient shall discontinue use of such Commercially Reasonable Royalty Interest Holder's intellectual property within thirty (30) days of the Division finding. The recipient shall not pay any remuneration to a Commercially Reasonable Royalty Interest Holder that does not qualify under the Medical Code and these rules, including but not limited to Rule M 231.2(B).

j. The Commercially Reasonable Royalty Interest Holder shall neither exercise control over nor be positioned so as to enable the exercise of control over the Medical Marijuana Business. Notwithstanding the foregoing, a Commercially Reasonable Royalty Interest Holder may influence the marketing, advertising, labeling and display of any product or line of products for which the Commercially Reasonably Royalty Interest exists so long as such influence is not inconsistent with the Medical Code or these rules.

J. Profit-Sharing Plan Documents. A Medical Marijuana Business offering licensed employees a share of the profits through a Profit-Sharing Plan must submit a list of all proposed participants in the Profit-Sharing Plan along with their names, addresses and occupational license numbers and submit a copy of all documentation regarding the Profit-Sharing Plan in connection with the Medical Marijuana Business' application:

1. The documents establishing the Profit-Sharing Plan must be complete and must fully incorporate all terms and conditions.

2. The following provisions must be included in the documents establishing the Profit-Sharing Plan:

    a. Any interest in a Medical Marijuana Business, whether held by a Profit-Sharing Plan Employee or any other person, must be acquired in accordance with the provisions of the Medical Code and/or Retail Code, as applicable, and the rules promulgated thereunder. The issuance of any contract or other interest in violation thereof shall be void. Any distributions from a Profit-Sharing Plan must be made in cash, not in the form of stock or other equity interests in the Medical Marijuana Business.

    b. No contract or other interest issued by the Medical Marijuana Business and no claim or charge therein or thereto shall be transferred except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. Any transfer in violation thereof shall be void.

    c. The Medical Marijuana Business shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which would lead to a finding that any Profit-Sharing Plan Employee does not qualify under the Medical Code and these rules, including but not limited to Rule M 231.2(B), to participate in the Profit-Sharing Plan.

    d. A Profit-Sharing Plan Employee shall disclose in writing to the Division and to the Medical Marijuana Business any and all disqualifying events, within ten days after occurrence of the event that could lead to a finding that the Profit-Sharing Plan Employee does not qualify or no longer qualifies under the Medical Code and these rules, including but not limited to Rule M 231.2(B), to participate in the Profit-Sharing Plan.

    e. A Medical Marijuana Business' or a Profit-Sharing Plan Employee's failure to make required disclosures may lead to a finding that the Profit-Sharing Plan is not approved, and may lead to a requirement that the Medical Marijuana Business terminate or modify the Profit-Sharing Plan.

    f. The Profit-Sharing Plan Employee agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval throughout the entire term of its relationship with the Medical Marijuana Business. The Profit-Sharing Plan Employee understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Profit-Sharing Plan. The Profit-Sharing Plan Employee agrees and acknowledges he or she has no entitlement to or expectation to Division approval of the Profit-Sharing Plan or the Profit-Sharing Plan Employee's participation in the plan. The Profit-Sharing Plan Employee further agrees that any administrative or judicial review of a determination by the Division approving or denying the Profit-Sharing Plan or the Profit-Sharing Plan Employee will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. Each Profit-Sharing Plan Employee further agrees and acknowledges that the Profit-Sharing Plan Employee shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. The Profit-Sharing Plan Employee also agrees and acknowledges that the Profit-Sharing Plan Employee may only request leave to intervene in an

administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. Furthermore, the Profit Sharing Plan Employee agrees and acknowledges that the Profit-Sharing Plan Employee may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Profit-Sharing Plan Employee. THE PROFIT-SHARING PLAN EMPLOYEE KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE PROFIT-SHARING PLAN OR THE PROFIT-SHARING PLAN EMPLOYEE BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE PROFIT-SHARING PLAN OR THE PROFIT-SHARING PLAN EMPLOYEE'S QUALIFICATIONS OR ACTIONS OF THE PROFIT-SHARING PLAN EMPLOYEE, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.

K. Qualified Institutional Investor Requirements. Before a Medical Marijuana Business may permit a Qualified Institutional Investor to own any portion of the Medical Marijuana Business, the Medical Marijuana Business must submit the following documentation to the Division in connection with the Medical Marijuana Business' application:

1. A description of the Qualified Institutional Investor's business and a statement as to why the Qualified Institutional Investor meets the definition of Qualified Institutional Investor in Rule M 103 and subsection 12-43.3-307.5(7), C.R.S.

2. A certification made under oath and the penalty of perjury by the Qualified Institutional Investor:

    a. That the ownership interests were acquired and are held for investment purposes only and were acquired and are held in the ordinary course of business as a Qualified Institutional Investor and not for the purposes of causing, directly or indirectly, the election of a majority of the board of directors, any change in the corporate charter, bylaws, management, policies, or operations of a Medical Marijuana Business.

    b. That the Qualified Institutional Investor is bound by and shall comply with the Medical Code and the rules adopted pursuant thereto, is subject to the jurisdiction of the courts of Colorado, and consents to Colorado as the choice of forum in the event any dispute, question, or controversy arises regarding the Qualified Institutional Investor's relationship with the Medical Marijuana Business or activities pursuant to the Medical Code and rules adopted pursuant thereto.

    c. The Qualified Institutional Investor agrees and acknowledges that its relationship with the Medical Marijuana Business is contingent upon Division approval throughout the entire term of its relationship with the Medical Marijuana Business. The Qualified Institutional Investor understands and acknowledges that approval by the Division is wholly discretionary and the Division may, at any time, deny approval of the Qualified Institutional Investor. The Qualified Institutional Investor agrees and acknowledges it has no entitlement to or expectation to Division approval of the Qualified Institutional Investor. The Qualified Institutional Investor further agrees that any administrative or judicial

review of a determination by the Division approving or denying the Qualified Institutional Investor will only occur through licensing or enforcement proceedings involving the Medical Marijuana Business. The Qualified Institutional Investor further agrees and acknowledges that the Qualified Institutional Investor shall only be entitled to notice of a denial or administrative action concerning the Medical Marijuana Business if the denial or administrative action is based upon, or directly related to, the qualifications or actions of the Qualified Institutional Investor. The Qualified Institutional Investor also agrees and acknowledges that the Qualified Institutional Investor may only request leave to intervene in an administrative proceeding against the Medical Marijuana Business, pursuant to subsection 24-4-105(2)(c), C.R.S., if the administrative proceeding is based upon, or directly related to, the qualifications or actions of the Qualified Institutional Investor. Furthermore, the Qualified Institutional Investor agrees and acknowledges that the Qualified Institutional Investor may only seek judicial review of an action against the Medical Marijuana Business, pursuant to subsection 24-4-106(4), C.R.S., if the administrative action is based upon, or directly related to, the qualifications or actions of the Qualified Institutional Investor. THE QUALIFIED INSTITUTIONAL INVESTOR KNOWINGLY, FREELY, AND VOLUNTARILY WAIVES ANY RIGHT OR CLAIM TO SEEK ANY INDEPENDENT REVIEW OF APPROVAL OR DENIAL OF THE QUALIFIED INSTITUTIONAL INVESTOR BY THE DIVISION, OR OF AN ADMINISTRATIVE ACTION AGAINST THE MEDICAL MARIJUANA BUSINESS, THAT IS BASED UPON, OR DIRECTLY RELATED TO, THE QUALIFICATIONS OR ACTIONS OF THE QUALIFIED INSTITUTIONAL INVESTOR, AND EXPRESSLY AGREES THAT THE ONLY ADMINISTRATIVE OR JUDICIAL REVIEW OF SUCH A DETERMINATION OR ACTION WILL OCCUR THROUGH A LICENSING OR ENFORCEMENT PROCEEDING FOR THE MEDICAL MARIJUANA BUSINESS.

d. An explanation of the basis of the signatory's authority to sign the certification and to bind the Qualified Institutional Investor to its terms.

3. The name, address, telephone number and any other information requested by the Division as required on its approved forms for the officers and directors, or their equivalent, of the Qualified Institutional Investor as well as those Persons that have direct control over the Qualified Institutional Investor's ownership interest in the Medical Marijuana Business.

4. The name, address, telephone number and any other information requested by the Division as required on its approved forms for each Person who has the power to direct or control the Qualified Institutional Investor's voting of its shares in the Medical Marijuana Business.

5. The name of each Person that beneficially owns 5 percent or more of the Qualified Institutional Investor's voting securities or other equivalent.

6. A list of the Qualified Institutional Investor's affiliates.

7. A list of all regulatory agencies with which the Qualified Institutional Investor files periodic reports, and the name, address, and telephone number of the individual, if known, to contact at each agency regarding the Qualified Institutional Investor.

8. A disclosure of all criminal or regulatory sanctions imposed during the preceding 10 years and of any administrative or court proceedings filed by any regulatory agency during the preceding 5 years against the Qualified Institutional Investor, its affiliates, any current officer or director, or any former officer or director whose tenure ended within the preceding 12 months. As to a former officer or director, such information need be

provided only to the extent that it relates to actions arising out of or during such person's tenure with the Qualified Institutional Investor or its affiliates.

9. A copy of any filing made under 16 U.S.C § 18a with respect to the acquisition or proposed acquisition of an ownership interest in the Medical Marijuana Business.

10. Any additional information requested by the Division.

Basis and Purpose – M 204

The statutory authority for this rule includes but is not limited to sections 12-43.3-104(1), 12-43.3-104(1.7), 12-43.3-104(12.4), 12-43.3-104(14.3), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(I), 12-43.3-202(2)(a)(XVI), , 12-43.3-202(2)(a)(XXI), 12-43.3-310(7), (8)(a), and (11), and 12-43.3-601(1), 12-43.3-307.5, 12-43.3-313 and 12-43.3-901, C.R.S. The purpose of this rule is to provide clarity regarding the nature of a Direct Beneficial Interest Owner and an Indirect Beneficial Interest Owner, and to clarify what factors the State Licensing Authority generally considers regarding the same. The Division will review all relevant information to determine ownership of a Medical Marijuana Business.

M 204 – Ownership Interests of a License: Medical Marijuana Businesses

A. Licenses Held By Direct Beneficial Interest Owners. Each Medical Marijuana Business License must be held by its Direct Beneficial Interest Owner(s). Each natural person other than a Qualified Limited Passive Investor must hold an Associated Key License. A Direct Beneficial Interest Owner shall not be a publicly traded company.

B. 100% Ownership.

1. The sum of the percentages of ownership of all Direct Beneficial Interest Owners of a Medical Marijuana Business and Qualified Institutional Investors must equal 100%.

a. Qualified Institutional Investors may hold ownership interests, in the aggregate, of 30% or less in the Medical Marijuana Business.

b. A Qualified Limited Passive Investor must be a natural person who is a United States citizen and may hold an ownership interest of less than five percent in the Medical Marijuana Business.

c. Each Direct Beneficial Interest Owner, including but not limited to each officer, director, managing member, or partner of a Medical Marijuana Business, must hold a current and valid Associated Key License. See Rule M 233 – Retail Code or Medical Code Occupational Licenses Required. Except that this requirement shall not apply to Qualified Limited Passive Investors.

d. With the exception of Qualified Institutional Investors, only Direct Beneficial Interest Owners may hold a partnership interest, limited or general, a joint venture interest, or ownership of a share or shares in a corporation or a limited liability company which is licensed.

e. In the event of the death, disability, disqualification, divestment, termination, or revocation of the license of a Direct Beneficial Interest Owner or of approval of a Qualified Institutional Investor, a Medical Marijuana Business shall have 45 days to submit a change of ownership application to the Division detailing the Licensee's plan for redistribution of ownership among the remaining Direct Beneficial Interest Owners and Qualified Institutional Investors. Such plan is subject to approval by the Division. If a change of ownership application is not

timely submitted, the Medical Marijuana Business and its Associated Key Licensee(s) may be subject to administrative action.

C. At Least One Associated Key License Required. No Medical Marijuana Business may operate or be licensed unless it has at least one Associated Key Licensee that is a Direct Beneficial Interest Owner who has been a Colorado resident for at least one year prior to application. Any violation of this requirement may be considered a license violation affecting public safety.

D. Loss Of Occupational License As An Owner Of Multiple Businesses. If an Associated Key License is suspended or revoked as to one Medical Marijuana Business or Retail Marijuana Establishment, that Owner's Occupational License shall be suspended or revoked as to any other Medical Marijuana Business or Retail Marijuana Establishment in which that Person possesses an ownership interest. See Rule M 233 – Medical Code or Retail Code Occupational Licenses Required.

E. Management Companies. Any Person contracted to manage the overall operation of a Licensed Premises must hold a Medical Marijuana Operator license.

F. Role of Managers. Associated Key Licensees may hire managers, and managers may be compensated on the basis of profits made, gross or net. A Medical Marijuana Business license may not be held in the name of a manager who is not a Direct Beneficial Interest Owner. A manager who does not hold an Associated Key License as a Direct Beneficial Interest Owner of the Medical Marijuana Business, must hold a Key License as an employee of the Medical Marijuana Business. Any change in manager must be reported to the Division and any local licensing authority before the new manager begins managing the Medical Marijuana Business. Additionally, a Medical Marijuana Operator may include management services as part of the operational services provided to a Medical Marijuana Business. A Medical Marijuana Business and its Direct Beneficial Interest Owners may be subject to license denial or administrative action, including but not limited to, fine, suspension or revocation of their license(s), based on the acts and omissions of any manager, Medical Marijuana Business Operator, or agents and employees thereof engaged in the operations of the Medical Marijuana Business.

G. Prohibited Third-Party Acts. No Licensee may employ, contract with, hire, or otherwise retain any Person, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct of the Licensee's behalf or for the Licensee's benefit if the Licensee is prohibited by law or these rules from engaging in such conduct itself.

1. A Licensee may be held responsible for all actions and omissions of any Person the Licensee employs, contacts with, hires, or otherwise retains, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit.

2. A Licensee may be subject to license denial or administrative action, including but not limited to fine, suspension, or revocation of its license(s), based on the act and/or omissions of any Person the Licensee employs, contacts with, hires, or otherwise retains, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit.

Basis and Purpose – M 204.5

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(I), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXI) and 12-43.3-202(3)(a)(XVI) and sections 12-43.3-104(1), 12-43.3-104(1.7), 12-43.3-305, 12-43.3-307, 12-43.3-307.5, 12-43.3-309, 12-43.3-310, 12-43.3-311 and 12-43.3-313, C.R.S. The purpose of this rule is to clarify the application, review and approval process for various types of Business Interests. The Division will review

all relevant information to determine ownership of, interests in, and control of a Medical Marijuana Business.

M 204.5 – Disclosure, Approval and Review of Business Interests

A. Business Interests. A Medical Marijuana Business shall disclose all Business Interests at the time of initial application and at the time of each renewal application. Business Interests include Financial Interests and Affiliated Interests. Any Financial Interest must be pre-approved by the Division. It shall be unlawful to fail to completely report all Business Interests in each license issued. It shall be unlawful for a person other than a Financial Interest holding an Associated Key License to exercise control over a Medical Marijuana Business or to be positioned so as to enable the exercise of control over a Medical Marijuana Business. Except that a Qualified Institutional Investor and a Qualified Limited Passive Investor may vote his, her or its shares in the Medical Marijuana Business.

B. Financial Interests. A Medical Marijuana Business shall not permit any Person to hold or exercise a Financial Interest in the Medical Marijuana Business unless and until such Person's Financial Interest has been approved by the Division. If a Medical Marijuana Business wishes to permit a Person to hold or exercise a Financial Interest, and that Person has not been previously approved in connection with an application for the Medical Marijuana Business, the Medical Marijuana Business shall submit a change of ownership or financial interest form approved by the Division. A Financial Interest shall include:

1. Any Direct Beneficial Interest Owner;

2. The following types of Indirect Beneficial Interest Owners:

    a. A Commercially Reasonable Royalty Interest Holder who receives, in the aggregate, a royalty of more than 30 percent; and

    b. A Permitted Economic Interest holder.

3. Control. Any other Person who exercises control or is positioned so as to enable the exercise of control over the Medical Marijuana Business must hold an Associated Key License. A natural person who exercises control or is positioned so as to enable the exercise of control over a Medical Marijuana Business shall include but shall not be limited to a natural person who:

    a. Bears the risk of loss and opportunity for profit;

    b. Has final decision making authority over any material aspect of the operation of the Medical Marijuana Business;

    c. Manages the overall operations of a Medical Marijuana Business or its Licensed Premises, or who manages a material portion of the Medical Marijuana Business or its Licensed Premises;

    d. Guarantees the Medical Marijuana Business' debts or production levels;

    e. Is a beneficiary of the Medical Marijuana Business' insurance policies;

    f. Receives the majority of the Medical Marijuana Business' profits as compared to other recipients of the Medical Marijuana Business' profits; or

g. Acknowledges liability for the Medical Marijuana Business' federal, state or local taxes.

C. Affiliated Interests. A Medical Marijuana Business shall disclose all Affiliated Interests in connection with each application for licensure, renewal or reinstatement of the Medical Marijuana Business. The Division may conduct such background investigation as it deems appropriate regarding Affiliated Interests. An Affiliated Interest shall include any Person who does not hold a Financial Interest in the Medical Marijuana Business and who has any of the following relationships with the Medical Marijuana Business:

1. The following Indirect Beneficial Interest Owners:

a. A Commercially Reasonable Royalty Interest Holder who receives, in the aggregate, a royalty of 30 percent or less;

b. A Profit Sharing Plan Employee; and

c. A Qualified Institutional Investor.

2. Any other Person who holds any other disclosable interest in the Medical Marijuana Business other than a Financial Interest. Such disclosable interests shall include but shall not be limited to an indirect financial interest, a lease agreement, a secured or unsecured loan, or security interest in fixtures or equipment with a direct nexus to the cultivation, manufacture, Transfer, transportation, testing, or researching of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. If the Division determines any Person disclosed as an Affiliated Interest should have been pre-approved as a Financial Interest, approval and further background investigation may be required. Additionally, the failure to seek pre-approval of a Financial Interest holder may form the basis for license denial or administrative action against the Medical Marijuana Business.

D. Secured Interest In Marijuana Prohibited. No Person shall at any time hold a secured interest in Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

Basis and Purpose – M 206

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-305, 12-43.3-310(7), and 12-43.3-310(13), C.R.S. The purpose of this rule is to clarify the application process for changing location of a Licensed Premises.

M 206 – Changing Location of the Licensed Premises: Medical Marijuana Businesses

A. Application Required to Change Location of Licensed Premises

1. A Direct Beneficial Interest Owner of a Medical Marijuana Business seeking to change the physical location or address of its Licensed Premises must make application to the Division for permission to change location of its Licensed Premises.

2. Such application shall:

a. Be made upon current forms prescribed by the Division;

b. Be complete in every material detail and include remittance of all applicable fees;

c. Be submitted at least 30 days prior to the proposed change;

d. Explain the reason for requesting such change;

e. Be supported by evidence that the application complies with any local licensing authority requirements; and

f. Contain a report of the relevant local licensing authority(-ies) in which the Medical Marijuana Business is to be situated, which report shall demonstrate the approval of the local licensing authority(-ies) with respect to the new location.

B. Permit Required Before Changing Location

1. No change of location shall be permitted until after the Division considers the application, and such additional information as it may require, and issues to the Applicant a permit for such change.

2. The permit shall be effective on the date of issuance, and the Licensee shall, within 120 days, change the location of its business to the place specified therein and at the same time cease to operate a Medical Marijuana Business at the former location. At no time may a Medical Marijuana Business operate or exercise any of the privileges granted pursuant to the license in both locations. For good cause shown, the 120 day deadline may be extended for an additional 120 days. If the Licensee does not change the location of its business within the time period granted by the Division, including any extension, the Licensee shall submit a new application, pay the requisite fees and receive a new permit prior to completing any change of the location of the business.

3. The permit shall be conspicuously displayed at the new location, immediately adjacent to the license to which it pertains.

4. Repealed.

C. General Requirements

1. Repealed.

2. An Applicant for change of location shall file a change of location application with the Division and pay the requisite change of location fee. *See* Rule M 207 - Schedule of Other Application Fees: All Licensees.

Basis and Purpose – M 207

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), 12-43.3-401(1)(a)-(e), and sections, 12-43.3-104, 12-43.3-310, 12-43.3-401, 12-43.3-501, and 12-43.3-502, C.R.S. The purpose of this rule is to clarify the schedules of application fees for Medical Marijuana Business Applicants.

M 207 – Schedule of Application Fees: Medical Marijuana Businesses

A. Base Medical Marijuana Application Fees

1. Medical Marijuana Center Application Fees

a. Type 1 Center (1-300 patients) - $6,000.00

b. Type 2 Center (301-500 patients) - $10,000.00

c. Type 3 Center (501 or more patients) - $14,000.00

2. Medical Marijuana-Infused Products Manufacturer Application Fee - $1,000.00

3. Optional Premises Cultivation Location Application Fee - $1,000.00

4. Medical Marijuana Testing Facility Application Fee - $1,000.00

5. Medical Marijuana Transporter Application Fee - $1,000.00

6. Medical Marijuana Business Operator Registration Application Fee - $1,000.00

7. Medical Marijuana Businesses Converting to Retail Marijuana Establishments. Medical Marijuana Center Applicants or Licensees that want to convert to Retail Marijuana Establishments should refer to 1 CCR 212-2, Rule R 207 – Schedule of Application Fees: Retail Marijuana Establishments.

B. Medical Marijuana Business Application Fees for Indirect Beneficial Interest Owners, Qualified Limited Passive Investors and Other Affiliated Interests

1. Affiliated Interest that is not an Indirect Beneficial Interest Owner - $200.00

2. Commercially Reasonable Royalty Interest Holder receiving, in the aggregate, a royalty of more than 30 percent - $400.00

3. Commercially Reasonable Royalty Interest Holder receiving, in the aggregate, a royalty of 30 percent or less - $200.00

4. Permitted Economic Interest - $400.00

5. Employee Profit Sharing Plan - $200.00

6. Qualified Limited Passive Investor

a. Standard limited initial background check - $75.00

b. Full background check for reasonable cause - $125.00

7. Qualified Institutional Investor - $200.00

C. When Application Fees Are Due. All application fees are due at the time a Medical Marijuana Business submits an application and/or at the time a Medical Marijuana Business submits an application for a new Financial Interest.

Basis and Purpose – M 210

The statutory authority for this includes but is not limited to sections 12-43.3-202(1)(a), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-104, 12-43.3-310, 12-43.3-401, 12-43.3-501, 12-43.3-502, 12-43.3-1101, and 12-43.3-1102, C.R.S. The purpose of this rule is to establish basic requirements for all Division applications and help the regulated community understand procedural licensing requirements.

M 210 – Schedule of Other Application Fees: All Licensees

A. Other Application Fees. The following other application fees apply:

1. Transfer of Ownership - New Owners - $1,600.00

2. Transfer of Ownership - Reallocation of Ownership - $1,000.00

3. Change of Corporation or LLC Structure - $800.00

4. Change of Trade Name - $50.00

5. Change of Location Application Fee - $500.00

6. Modification of Licensed Premises - $100.00

7. Duplicate Business License - $20.00

8. Duplicate Occupational License - $20.00

9. Off Premises Storage Permit - $1,500.00

10. Medical Marijuana Transporter Off Premises Storage Permit - $2,200.00

11. Responsible Vendor Program Provider Application Fee: $850.00

12. Responsible Vendor Program Provider Renewal Fee: $350.00

13. Responsible Vendor Program Provider Duplicate Certificate Fee: $50.00

B. When Other Application Fees Are Due. All other application fees are due at the time the application and/or request is submitted.

C. Subpoena Fee - See Rule M 106 – Subpoena Fees

Basis and Purpose – M 231

The statutory authority for this rule includes but is not limited to sections 12-43.3-201(4), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(4), 12-43.3-310(7), and 24-18-105(3), and 12-43.3-104, 12-43.3-306, 12-43.3-307, 12-43.307.5, 12-43.3-401 24-76.5-101 et. seq, C.R.S. The purpose of this rule is to clarify the qualifications for licensure, including, but not limited to, the requirement for a fingerprint-based criminal history record check for all Direct Beneficial Interest Owners, contractors, employees, and other support staff of licensed entities.

M 231 – Qualifications for Licensure and Residency

A. Any Applicant may be required to establish his or her identity and age by any document required for a determination of Colorado residency, United States citizenship or lawful presence.

B. Maintaining Ongoing Licensing Qualification: Duty to Report Offenses. An Applicant or Licensee shall notify the Division in writing of any felony criminal charge and felony conviction against such Person within ten days of such person's arrest, felony summons, and within ten days of the disposition of any arrest or summons. Failure to make proper notification to the Division may be grounds for disciplinary action. Applicants and Licensees shall notify the Division within ten days of any other event that renders the Applicant or Licensee no longer qualified under these rules. Licensees shall cooperate in any investigation conducted by the Division. This duty to report includes, but is not limited to, deferred sentences or judgments that are not sealed. If the Division lawfully finds a disqualifying event and an Applicant asserts that the record was sealed, the

Division may require the Applicant to provide proof from a court evidencing the sealing of the case.

C. Application Forms Accessible to Law Enforcement and Licensing Authorities. All application forms supplied by the Division and filed by an Applicant for licensure shall be accessible by the State Licensing Authority, local licensing authorities, and any state or local law enforcement agent.

D. Associated Key Licenses. Each Direct Beneficial Interest Owner who is a natural person, including but not limited to each officer, director, member or partner of a Closely Held Business Entity, must apply for and hold at all times a valid Associated Key License. Except that these criteria shall not apply to Qualified Limited Passive Investors, who are not required to hold Associated Key Licenses. Each such Direct Beneficial Interest Owner must establish that he or she meets the following criteria before receiving an Associated Key License:

1. The Applicant has paid the annual application and licensing fees;

2. The Applicant's criminal history indicates that he or she is of Good Moral Character;

3. The Applicant is not employing, or financed in whole or in part by any other Person whose criminal history indicates that he or she is not of Good Moral Character;

4. The Applicant is at least 21 years of age;

5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment, if applicable;

6. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;

7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a Medical Marijuana Business.

8. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer; except that the State Licensing Authority may grant a license to a person if the Applicant has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony of the Applicant were convicted of the offense on the date he or she applied for licensure'

9. The Applicant does not employ another person who does not have a valid Occupational License issued pursuant to either the Medical Code or Retail Code;

10. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority;

11. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for individuals, Retail Marijuana Establishments and/or Medical Marijuana Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application;

12. The premises that the Applicant proposes to be licensed is not currently licensed as a retail food establishment or wholesale food registrant;

13. The Applicant either:

    a. Has been a resident of Colorado for at least one year prior to the date of the application, or

    b. Has been a United States citizen since a date prior to the date of the application and has received a Finding of Suitability from the Division prior to filing the application. See Rule M 231.1 – Finding of Suitability, Residency and Reporting Requirements for Direct Beneficial Interest Owners; Rule M 232 – Factors Considered When Determining Residency and Citizenship: Individuals.

14. For Associated Key Licensees who are owners of a Closely Held Business Entity, the Applicant is a United States citizen.

E. Occupational Licenses. An Occupational License Applicant who is not applying for an Associated Key License must establish that he or she meets the following criteria before receiving an Occupational License:

1. The Applicant has paid the annual application and licensing fees;

2. The Applicant's criminal history indicates that he or she is of Good Moral Character;

3. The Applicant is at least 21 years of age;

4. An Applicant is currently a resident of Colorado. See Rule M 232 – Factors Considered When Determining Residency and Citizenship: Individuals;

5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment;

6. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;

7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a Medical Marijuana Business;

8. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer; except that the State Licensing Authority may grant a license to a person if the person has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony of the person were convicted of the offense on the date he or she applied for licensure;

9. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority; and

10. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for occupational licensees, Medical Marijuana Businesses and/or Retail Marijuana Establishments licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant’s application.

F. Current Medical Marijuana Occupational Licensees.

1. An individual who holds a current, valid Occupational License issued pursuant to the Medical Code may also work in a Retail Marijuana Establishment; no separate Occupational License is required.

2. An individual who holds a current, valid Occupational License issued pursuant to the Retail Code after July 1, 2015 may also work in a Medical Marijuana Business; no separate Occupational License is required.

G. Associated Key License Privileges. A person who holds an Associated Key License must associate that license separately with each Medical Marijuana Business or Retail Marijuana Establishment with which the person is associated by submitting a form approved by the Division. A person who holds an Associated Key License may exercise the privileges of a licensed employee in any licensed Medical Marijuana Business or Retail Marijuana Establishment in which they are not an owner so long as the person does not exercise privileges of ownership.

H. Qualified Limited Passive Investor. An Applicant who wishes to be a Qualified Limited Passive Investor and hold an interest in a Medical Marijuana Business as a Direct Beneficial Interest Owner must establish that he or she meets the following criteria before the ownership interest will be approved:

1. He or she is a natural person;

2. The Applicant qualifies under Rule M 231.2(B);

3. He or she has been a United States citizen since a date prior to the date of the application, and

4. He or she has signed an affirmation of passive investment.

I. Workforce Training or Development Residency Exempt License. An Applicant who wishes to obtain a workforce development or training exemption to the license residency requirement may only apply for a Support License or Key License and must:

1. Submit a complete application on the Division's approved forms;

2. Establish he or she meets the licensing criteria of Rule M 231(E)(1)-(3) and 231(E)(5)-(10) for Occupational Licensees;

3. Provide evidence of proof of lawful presence; and

4. Provide a complete Workforce Training or Development Affirmation form executed under penalty of perjury.

Basis and Purpose – M 231.1

The statutory authority for this rule includes but is not limited to sections 12-43.3-201(4), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(4), 12-43.3-310(7), and 24-18-105(3), and sections 12-43.3-104(1), 12-43.3-104(12.4), 12-43.3-307, 12-43.3-307.5, 12-43.3-313, 12-43.3-401, and 24-76.5-101 et. seq,, C.R.S. The purpose of this rule is to clarify the qualifications for Direct Beneficial Interest Owners.

M 231.1 – Finding of Suitability, Residency and Reporting Requirements for Direct Beneficial Interest Owners

A. Finding of Suitability – Non-Resident Direct Beneficial Interest Owners. A natural person, owner, shareholder, director, officer, member or partner of an entity that intends to apply to become a Direct Beneficial Interest Owner who has not been a resident of Colorado for at least one year prior to the application shall first submit a request to the State Licensing Authority for a finding of suitability to become a Direct Beneficial Interest Owner as follows:

1. A request for a finding of suitability for a non-resident natural person shall be submitted on the forms prescribed by the State Licensing Authority.

2. A natural person or all owners, shareholders, directors, officers, members or partners of an entity who have not been a resident of Colorado for at least one year shall obtain a finding of suitability prior to submitting an application to become a Direct Beneficial Interest Owner to the State Licensing Authority. d.

3. A finding of suitability is valid for one year from the date it is issued by the Division. If more than one year has passed since the Division issued a finding of suitability to a natural person, owner, shareholder, director, officer, member, or partner of an entity that intends to apply to become a Direct Beneficial Interest Owner who has not been a resident of Colorado for at least one year prior to the application, then such applicant shall submit a new request for a finding of suitability to the State Licensing Authority and obtain a new finding of suitability before submitting any application to become a Direct Beneficial Interest Owner to the State Licensing Authority. All recipients of a finding of suitability shall disclose in writing to the Division any and all disqualifying events within 10 days after occurrence of the event that could lead to a finding that the recipient no longer qualifies to become a Direct Beneficial Interest Owner.

4. The failure of a non-Colorado resident, who is not already a Direct Beneficial Interest Owner, to obtain a finding of suitability within the year prior to submission of an application to become a Direct Beneficial Interest Owner to the State Licensing Authority shall be grounds for denial of the application.

B. Number of Permitted Direct Beneficial Interest Owners.

1. A Medical Marijuana Business may be comprised of an unlimited number of Direct Beneficial Interest Owners that have been residents of Colorado for at least one year prior to the date of the application.

2. On and after January 1, 2017, a Medical Marijuana Business that is comprised of one or more Direct Beneficial Interest Owners who have not been Colorado residents for at least one year is limited to no more than fifteen Direct Beneficial Interest Owners, each of whom is a natural person. Further, a Medical Marijuana Business that is comprised of one or more Direct Beneficial Interest Owners who have not been Colorado residents for at least one year shall have at least one officer who is a Colorado resident. All officers with day-to-day operational control over a Medical Marijuana Business must be Colorado residents for at least one year, must maintain their Colorado residency during the period while they have day-to-day operational control over the Medical Marijuana Business and shall be licensed as required by the Medical Code. Rule 231 – Qualifications for Licensure and Residency: Individuals.

C. Notification of Change of Residency. A Medical Marijuana Establishment with more than fifteen Direct Beneficial Interest Owners shall provide thirty days prior notice to the Division of any Direct Beneficial Interest Owners' intent to change their residency to a residency outside Colorado. A Medical Marijuana Business with no more than fifteen Direct Beneficial Interest Owners shall notify the Division of the change of residency of any Direct Beneficial Interest Owner at the time of its license renewal. Failure to provide timely notice pursuant to this rule may lead to

administrative action against the Medical Marijuana Business and its Direct Beneficial Interest Owners.

D. A Direct Beneficial Interest Owner shall not be a publicly traded company.

Basis and Purpose – M 231.2

The statutory authority for this rule includes but is not limited to sections 12-43.3-104(1.7), 12-43.3-104(12.4), 12-43.3-201(4), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXI), 12-43.3-307.5, 24-18-105(3), and 24-76.5-101 et. seq., C.R.S. The purpose of this rule is to clarify the qualifications for an Indirect Beneficial Interest Owner other than a Permitted Economic Interest.

M 231.2 – Qualifications for Indirect Beneficial Interest Owners and Qualified Limited Passive Investors

A. General Requirements

1. An Applicant applying to become a Commercially Reasonable Royalty Interest holder who receives a royalty of more than 30 percent or the holder of a Permitted Economic Interest must be pre-approved by the Division.

2. An Applicant applying to become an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the Applicant made misstatements, omissions, misrepresentations, or untruths in the application. This type of conduct may be considered as the basis of additional administrative action against the Applicant and the Medical Marijuana Business.

3. The Division may deny the application when the Applicant fails to provide any requested information by the Division's deadline.

4. The Division's determination that an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor is qualified constitutes a revocable privilege held by the Medical Marijuana Business. The burden of proving the Indirect Beneficial Interest Owner or Qualified Limited Passive Investor is qualified rests at all times with the Medical Marijuana Business Applicant. Indirect Beneficial Interest Owners and Qualified Limited Passive Investors are not separately licensed by the Division. Any administrative action regarding an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor may be taken directly against the Medical Marijuana Business.

5. Permitted Economic Interest Fingerprints Required. Any individual applying to hold his or her first Permitted Economic Interest shall be fingerprinted for a criminal history record check. In the Division's discretion, an individual may be required to be fingerprinted again for additional criminal history record checks.

6. No publicly traded company can be an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor.

B. Qualification. The Division may consider the following non-exhaustive list of factors to determine whether an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor is qualified:

1. The Applicant's criminal history indicates that he or she is of Good Moral Character;

2. The Applicant is at least 21 years of age;

3. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment, if applicable;

4. The Applicant is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;

5. The Applicant is not currently subject to or has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer, except, in the Division's discretion, a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony if the Person were convicted of the offense on the date he or she applied may not disqualify an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor;

6. The Applicant is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority;

7. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for individuals, Medical Marijuana Businesses and/or Retail Marijuana Establishments licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.

8. The Applicant has provided all documentation requested by the Division to establish qualification to be an Indirect Beneficial Interest Owner.

C. Maintaining Qualification:

1. An Indirect Beneficial Interest Owner or Qualified Limited Passive Investor shall notify the Division in writing of any felony criminal charge and felony conviction against such person within ten days of such person's arrest or felony summons, and within ten days of the disposition of any arrest or summons. Failure to make proper notification to the Division may be grounds for disciplinary action. This duty to report includes, but is not limited to, deferred sentences, prosecutions, or judgments that are not sealed. If the Division lawfully finds a disqualifying event and the individual asserts that the record was sealed, the Division may require the individual to provide proof from a court evidencing the sealing of the case

2. An Indirect Beneficial Interest Owner, Qualified Limited Passive Investor and Medical Marijuana Business shall cooperate in any investigation into whether an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor continues to be qualified that may be conducted by the Division.

D. Divestiture of Indirect Beneficial Interest Owner or Qualified Limited Passive Investor. If the Division determines an Indirect Beneficial Interest Owner or Qualified Limited Passive Investor is not permitted to hold their interest, the Medical Marijuana Business shall have 60 days from such determination to divest the Indirect Beneficial Interest Owner or Qualified Limited Passive Investor. The Division may extend the 60-day deadline for good cause shown. Failure to timely divest any Indirect Beneficial Interest Owner or Qualified Limited Passive Investor the Division determines is not qualified, or is no longer qualified, may constitute grounds for denial of license or administrative action against the Medical Marijuana Business and/or its Associated Key Licensee(s).

M 300 Series – The Licensed Premises

Basis and Purpose – M 301

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XX), and 12-43.3-105, C.R.S. The purpose of this rule is to establish regulations governing Limited Access Areas for inside a Licensed Premises. In addition, this rule clarifies that businesses and individuals cannot use the visitor system as a means to employ an individual who does not possess a valid and current Occupational License.

M 301 – Limited Access Areas

A. Proper Display of License Badge. All persons in a Limited Access Area as provided for in section 12-43.3-105, C.R.S., shall be required to hold and properly display a current license badge issued by the Division at all times. Proper display of the license badge shall consist of wearing the badge in a plainly visible manner, at or above the waist, and with the photo of the Licensee visible. The Licensee shall not alter, obscure, damage, or deface the badge in any manner.

B. Visitors in Limited Access Areas

1. Prior to entering a Limited Access Area, all visitors, including outside vendors, contractors or others, must obtain a visitor identification badge from management personnel of the Licensee that shall remain visible while in the Limited Access Area.

2. Visitors shall be escorted by the Medical Marijuana Business's licensed personnel at all times. No more than five visitors may be escorted by a single employee. Except that trade craftspeople not normally engaged in the business of cultivating, processing or selling Medical Marijuana need not be accompanied on a full-time basis, but only reasonably monitored.

2.1 A Medical Marijuana Business and a Licensee employed by the Medical Marijuana Business shall report any discovered plan of or other act or omission by any visitor or other Person: (1) to commit theft, burglary, underage sales, diversion of Medical Marijuana or Medical Marijuana Infused-Product, or other crime related to the operation of the subject Medical Marijuana Business; (2) to compromise the integrity of the Inventory Tracking System; or (3) that results in serious bodily injury to any Person on the Licensed Premises of the Medical Marijuana Business or otherwise creates a material risk to public health or safety Such discovered plan or other act or omission shall be reported to the Division in accordance with Rule M 904 – Medical Marijuana Business Reporting Requirements.

3. The Licensee shall maintain a log of all visitor activity, for any purpose, within the Limited Access Area and shall make such logs available for inspection by the Division or relevant local licensing authority.

4. All visitors admitted into a Limited Access Area must provide acceptable proof of age and must be at least 21 years of age. See Rule M 405 – Acceptable Forms of Identification for Medical Sales.

5. The Licensee shall check an acceptable form of identification for all visitors to verify that the name on the identification matches the name in the visitor log. See Rule M 405 – Acceptable Forms of Identification for Medical Sales

6. A Licensee may not receive consideration or compensation for permitting a visitor to enter a Limited Access Area.

7. Use of a visitor badge to circumvent the Occupational License requirements of Rule M 233 is prohibited and may constitute a license violation affecting public safety.

C. Required Signage. All areas of ingress and egress to Limited Access Areas on the Licensed Premises shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Do Not Enter - Limited Access Area – Access Limited to Licensed Personnel and Escorted Visitors".

D. Diagram for Licensing Licensed Premises. All Limited Access Areas shall be clearly identified to the Division or relevant local licensing authority and described by the filing of a diagram of the Licensed Premises reflecting walls, partitions, counters and all areas of ingress and egress. The diagram shall also reflect all Propagation, cultivation, manufacturing, and Restricted Access Areas. See Rule M 901 – Business Records Required.

E. Modification of a Limited Access Area. A Licensee's proposed modification of designated Limited Access Areas shall be approved by Division or local licensing authorities. See Rule M 303 – Changing, Altering, or Modifying Licensed Premises.

F. Law Enforcement Personnel Authorized. Notwithstanding the requirements of subsection A of this Rule, nothing shall prohibit investigators and employees of the Division, authorities from local licensing authority or any state or local law enforcement agency, for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose, from entering a Limited Access Area upon presentation of official credentials identifying them as such.

Basis and Purpose – M 302

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), and 12-43.3-308(1)(b), C.R.S. The purpose of this rule is to establish and clarify the means by which the Licensee can establish lawful possession of the Licensed Premises.

M 302 – Possession of Licensed Premises

A. Evidence of Lawful Possession. Persons licensed pursuant to sections 12-43.3-402, 12-43.3-403, 12-43.3-404, 12-43.3-405, 12-43.3-406, 12-43.3-407, or 12-43.3-408, C.R.S., or those making application for such licenses, must demonstrate proof of lawful possession of the premises to be licensed or Licensed Premises. Evidence of lawful possession consists of properly executed deeds of trust, leases, or other written documents acceptable to the State Licensing Authority and local licensing authorities.

B. Relocation Prohibited. The Licensed Premises shall only be those geographical areas that are specifically and accurately described in executed documents verifying lawful possession. Licensees are not authorized to relocate to other areas or units within a building structure without first filing a change of location application and obtaining approval from the Division and the local licensing authority. Licensees shall not add additional contiguous units or areas, thereby altering the initially-approved premises, without filing an Application to modify the Licensed Premises on current forms prepared by the Division, including any applicable processing fee. See Rule M 303 - Changing, Altering, or Modifying Licensed Premises.

C. Subletting Not Authorized. Licensees are not authorized to sublet any portion of a Licensed Premises for any purpose, unless all necessary applications to modify the existing Licensed Premises to accomplish any subletting have been approved by the Division and local licensing authority.

M 304 – Repealed.

Basis and Purpose – M 304.1

The statutory authority for this Rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-104(1)(a)(V), 12-43.4-202(b), 12-43.4-401(2), 12-43.4-404(2), 12-43.3-406, 12-43.4-405, and 12-43.4-406, C.R.S.. The purpose of this rule is to establish guidelines for the manner in which a Medical Marijuana Business may share its existing Licensed Premises with a Licensed Retail Marijuana Establishment, and to ensure the proper separation of a Medical Marijuana Business operation from a Retail Marijuana Establishment operation.

M 304.1 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation

A. Co-Located Medical Marijuana Centers and Retail Marijuana Stores.

1. Medical Marijuana Center that authorizes patients that are over the age of 21. A Medical Marijuana Center that authorizes only Medical Marijuana patients who are over the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate at the same location under the following circumstances:

    a. The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;

    b. The Medical Marijuana Center and Retail Marijuana Store are commonly owned;

    c. The Medical Marijuana Center and Retail Marijuana Store shall maintain physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Product, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory;

    d. The Medical Marijuana Center and Retail Marijuana Store shall maintain separate displays between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Product, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory;

    e. Record-keeping, inventory tracking, packaging, and labeling for the Medical Marijuana Center and Retail Marijuana Store shall enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana Center from the inventories and business transactions of the Retail Marijuana Store; and

    f. The Medical Marijuana Center shall post and maintain signage the clearly conveys that persons under the age of 21 years may not enter.

2. Medical Marijuana Center that authorizes patients under the age of 21. A Medical Marijuana Center that authorizes Medical Marijuana Patients under the age of 21 years to be on the premises may operate in the same location with a Retail Marijuana Store under the following circumstances:

    a. The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;

b. The Medical Marijuana Center and Retail Marijuana Store are commonly owned;

c. The Medical Marijuana Center and the Retail Marijuana Store maintain physical separation, including separate entrances and exits, between their respective Restricted Access Areas;

d. No point of sale operations occur at any time outside the physically separated Licensed Premises;

e. All Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product in a Restricted Access Area must be physically separated from all Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product in a Restricted Access Area, and such physical separation must include separate entrances and exits;

f. Any display areas shall be located in the physically separated Restricted Access Areas;

g. In addition to the physically separated sales and display areas, the Medical Marijuana Center and Retail Marijuana Store shall maintain physical or virtual separation for storage of Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Product and other Medical Marijuana-related inventory from storage of Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products and other Retail Marijuana-related inventory; and

h. Record-keeping, inventory tracking, packaging, and labeling for the Medical Marijuana Center and Retail Marijuana Store shall enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana Center from the inventories and business transactions of the Retail Marijuana Store.

B. Co-located Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;

2. The Optional Premises Cultivation Operation and the Retail Marijuana Cultivation Facility are commonly owned;

3. The co-located Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility shall maintain either physical or virtual separation between (i) Medical Marijuana and Medical Marijuana Concentrate and (ii) and Retail Marijuana and Retail Marijuana Concentrate; and

4. Record keeping, inventory tracking, packaging and labeling for the Optional Premises Cultivation Operation and Retail Marijuana Cultivation Facility must enable the Division and relevant local licensing authority to clearly distinguish the inventories and business transactions of the Optional Premises Cultivation Operation from the Retail Marijuana Cultivation Facility.

C. Co-located Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility. A Medical Marijuana-Infused Products Manufacturer and a Retail

Marijuana Products Manufacturing Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant local licensing authority and local jurisdiction permit a dual operation at the same location;

2. The Medical Marijuana-Infused Products Manufacturer and the Retail Marijuana Products Manufacturing Facility are commonly owned;

3. The Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Products and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products and other Retail Marijuana-related inventory. Nothing in this Rule prohibits a co-located Retail Marijuana Products Manufacturing Facility and Medical Marijuana-Infused Products Manufacturer from sharing raw ingredients in bulk, for example flour or sugar, except Retail Marijuana and Medical Marijuana may not be shared under any circumstances; and

4. Record keeping, inventory tracking, packaging and labeling for the Medical Marijuana-Infused Products Manufacturer and Retail Marijuana Products Manufacturing Facility must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana-Infused Product Manufacturer from the Retail Marijuana Product Manufacturing Facility.

D. Co-located Medical Marijuana Testing Facility and Retail Marijuana Testing Facility. A Medical Marijuana Testing Facility and a Retail Marijuana Testing Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant local licensing authority and local licensing jurisdiction permit dual operation at the same location;

2. The Medical Marijuana Testing Facility and Retail Marijuana Testing Facility are identically owned;

3. The Medical Marijuana Testing Facility and Retail Marijuana Testing Facility shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Product and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products and other Retail Marijuana-related inventory; and

4. Record keeping, inventory tracking, packaging and labeling for the Medical Marijuana Testing Facility and Retail Marijuana Testing Facility must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana Testing Facility from the Retail Marijuana Testing Facility.

E. Co-Located Medical Marijuana Transporter and Retail Marijuana Transporter. A Medical Marijuana Transporter and a Retail Marijuana Transporter may share a single Licensed Premises and operate dual transporting, logistics, and temporary storage business operation at the same location under the following circumstances:

1. The relevant local licensing authority and local licensing jurisdiction permit dual operation at the same location;

2. The Medical Marijuana Transporter and Retail Marijuana Transporter are identically owned;

3. The Medical Marijuana Transporter and Retail Marijuana Transporter shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana-Infused Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products and other Retail Marijuana-related inventory; and

4. Record keeping, inventory tracking, packaging and labeling for the Medical Marijuana Transporter and Retail Marijuana Transporter must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of the Medical Marijuana Transporter from the Retail Marijuana Transporter.

F. Violation of this Rule may be considered a violation affecting public safety.

Basis and Purpose – M 305

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure adequate control of the Licensed Premises and the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product contained therein. This rule also establishes the minimum guidelines for security requirements for alarm systems, and commercial locking mechanisms for maintaining adequate security.

M 305 – Security Alarm Systems and Lock Standards

A. Security Alarm Systems – Minimum Requirements

1. Each Licensed Premises shall have a Security Alarm System, installed by an Alarm Installation Company, on all perimeter entry points and perimeter windows.

2. Each Licensee must ensure that all of its Licensed Premises are continuously monitored. Licensees may engage the services of a Monitoring Company to fulfill this requirement.

3. The Licensees shall maintain up to date and current records and existing contracts on the Licensed Premises that describe the location and operation of each Security Alarm System, a schematic of security zones, the name of the Alarm Installation Company, and the name of any Monitoring Company. See Rule M 901 – Business Records Required.

4. Upon request, Licensees shall make available to agents of the Division or relevant local licensing authority or other state or local law enforcement agency, for a purpose authorized by the Medical Code or any other state or local law enforcement purpose, all information related to Security Alarm Systems, Monitoring, and alarm activity.

5. Any outdoor or greenhouse Optional Premises Cultivation Operation, or outdoor or greenhouse Marijuana Research and Development Cultivation, is a Limited Access Area and must meet all of the requirements for Security Alarm Systems described in this rule. An outdoor or greenhouse Optional Premises Cultivation Operation or outdoor or greenhouse Marijuana Research and Development Cultivation must provide sufficient security measures to demonstrate that outdoor or greenhouse areas are not readily accessible by unauthorized individuals. It shall be the responsibility of the Licensee to maintain physical security in a manner similar to an Optional Premises Cultivation Operation or Marijuana Research and Development Cultivation located in an indoor Licensed Premises so it can be fully secured and alarmed. The fencing requirements

shall, at a minimum, include, perimeter fencing designed to prevent the general public from entering the Limited Access Areas and shall meet at the least the following requirements:

a. The entire Limited Access Area shall be surrounded by a fence that measures at least eight feet from the ground to the top of the fence and is constructed of at least six gauge or higher metal chain link fence or another similarly secure material but may not be wood. All support posts shall be steel and securely anchored.

b. All entry gates shall measure at least eight feet from the ground to the top of the entry gate and shall be constructed of six gauge or higher metal chain link fence or a similarly secure material but may not be wood.

c. The fence shall obscure the Limited Access Area so that it is not easily viewed from outside the fence.

d. The perimeter of the fence shall be surrounded with lights illuminating all sides of the fence for at least 20 feet from the fence. The required lights may be, but are not required to be, motion sensing.

e. A Licensee may, in writing, request that the Division waive one or more of the security requirements described in subparagraphs (a) through (d) of this Rule, by submitting on a form prescribed by the Division a security waiver request for Division approval. The Division may, in its discretion and on a case by case basis, approve the security waiver if it finds that the alternative safeguard proposed by the Licensee meets the goals of the above security requirements. Approved security waivers expire at the same time as the underlying License. The Licensee's request for a waiver shall include:

   i. The specific rules and subsections of a rule that is requested to be waived;

   ii. The reason for the waiver;

   iii. A description of an alternative safeguard the Licensee will implement in lieu of the requirement that is the subject of the waiver; and

   iv. An explanation of how and why the alternative safeguard accomplishes the goals of the security rules, specifically public safety, prevention of diversion, accountability, and prohibiting access to minors.

f. During the period January 1, 2018, to January 1, 2019, a Licensee that is currently in compliance with the Security Alarm Systems requirements will not be required to comply with this revised Rule M 305. Compliance with this revised Rule M 305 shall be required effective January 1, 2019.

B. Lock Standards – Minimum Requirement

1. At all points of ingress and egress, the Licensee shall ensure the use of a commercial-grade, non-residential door locks.

2. Any outdoor or greenhouse Optional Premises Cultivation Operation, or outdoor or greenhouse Marijuana Research and Development Cultivation, must meet all of the requirements for the lock standards described in this rule.

Basis and Purpose – M 306

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X), 12-43.3-202(2)(a)(XV), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure adequate control of the Licensed Premises and the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product contained therein. This rule also establishes the minimum guidelines for security requirements for video surveillance systems for maintaining adequate security.

M 306 – Video Surveillance

A. Minimum Requirements The following video surveillance requirements shall apply to all Medical Marijuana Businesses:

1. Prior to exercising the privileges of a Medical Marijuana Business, an Applicant must install fully operational video surveillance and camera recording system. The recording system must record in digital format and meet the requirements outlined in this rule.

2. All video surveillance records and recordings must be stored in a secure area that is only accessible to a Licensee's management staff.

3. Video surveillance records and recordings must be made available upon request to the Division, the relevant local licensing authority, or any other state or local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.

4. Video surveillance records and recordings of point-of-sale areas shall be held in confidence by all employees and representatives of the Division, except that the Division may provide such records and recordings to the relevant local licensing authority, or any other state or local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.

B. Video Surveillance Equipment

1. Video surveillance equipment shall, at a minimum, consist of digital or network video recorders, cameras capable of meeting the recording requirements described in this Rule, video monitors, digital archiving devices, and a color printer capable of delivering still photos.

2. All video surveillance systems must be equipped with a failure notification system that provides prompt notification to the Licensee of any prolonged surveillance interruption and/or the complete failure of the surveillance system.

3. Licensees are responsible for ensuring that all surveillance equipment is properly functioning and maintained so that the playback quality is suitable for viewing and the surveillance equipment is capturing the identity of all individuals and activities in the monitored areas.

4. All video surveillance equipment shall have sufficient battery backup to support a minimum of four hours of recording in the event of a power outage.

C. Placement of Cameras and Required Camera Coverage

1. Camera coverage is required for all Limited Access Areas, point-of-sale areas, security rooms, all points of ingress and egress to Limited Access Areas, all areas where Medical

Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product is displayed for sale, and all points of ingress/egress to the exterior of the Licensed Premises.

2. Camera placement shall be capable of identifying activity occurring within 20 feet of all points of ingress and egress and shall allow for the clear and certain identification of any individual and activities on the Licensed Premises.

3. At each point-of-sale location, camera coverage must enable recording of the patients, caregiver or customer(s) and employee(s) facial features with sufficient clarity to determine identity.

4. All entrances and exits to the facility shall be recorded from both indoor and outdoor vantage points.

5. The system shall be capable of recording all pre-determined surveillance areas in any lighting conditions. If the Licensed Premises has a Medical Marijuana cultivation area, a rotating schedule of lighted conditions and zero-illumination can occur as long as ingress and egress points to Flowering areas remain constantly illuminated for recording purposes.

6. Areas where Medical Marijuana is grown, tested, cured, manufactured, researched, or stored shall have camera placement in the room facing the primary entry door at a height which will provide a clear unobstructed view of activity without sight blockage from lighting hoods, fixtures, or other equipment.

7. Cameras shall also be placed at each location where weighing, packaging, transport, preparation, or tagging activities occur.

8. At least one camera must be dedicated to record the access points to the secured surveillance recording area.

9. All outdoor cultivation areas must meet the same video surveillance requirements applicable to any other indoor Limited Access Areas.

D. Location and Maintenance of Surveillance Equipment

1. The surveillance room or surveillance area shall be a Limited Access Area.

2. Surveillance recording equipment must be housed in a designated, locked and secured room or other enclosure with access limited to authorized employees, agents of the Division and relevant local licensing authority, state or local law enforcement agencies for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose, and service personnel or contractors.

3. Licensees must keep a current list of all authorized employees and service Personnel who have access to the surveillance system and/or room on the Licensed Premises. Licensees must keep a surveillance equipment maintenance activity log on the Licensed Premises to record all service activity including the identity of the individual(s) performing the service, the service date and time and the reason for service to the surveillance system.

4. Off-site Monitoring and video recording storage of the Licensed Premises by the Licensee or an independent third-party is authorized as long as standards exercised at the remote location meets or exceeds all standards for on-site Monitoring.

5. Each Medical Marijuana Licensed Premises located in a common or shared building must have a separate surveillance room/area that is dedicated to that specific Licensed Premises. Commonly-owned Medical Marijuana Businesses located in the same local jurisdiction may have one central surveillance room located at one of the commonly owned Licensed Premises which simultaneously serves all of the commonly-owned Medical Marijuana Businesses. The facility that does not house the central surveillance room is required to have a review station, printer, and map of camera placement on the premises. All minimum requirements for equipment and security standards as set forth in the section apply to the review station.

6. A co-located Medical Marijuana Business and a Retail Marijuana Establishment may have one central surveillance room located at the shared Licensed Premises. See Rule M 304 – Medical Marijuana Business and Retail Marijuana Establishment: Shared Licensed Premises and Operational Separation.

E. Video Recording and Retention Requirements

1. All camera views of all Limited Access Areas must be continuously recorded 24 hours a day. The use of motion detection is authorized when a Licensee can demonstrate that monitored activities are adequately recorded.

2. All surveillance recordings must be kept for a minimum of 40 days and be in a format that can be easily accessed for viewing. Video recordings must be archived in a format that ensures authentication of the recording as legitimately-captured video and guarantees that no alteration of the recorded image has taken place.

3. The Licensee's surveillance system or equipment must have the capabilities to produce a color still photograph from any camera image, live or recorded, of the Licensed Premises.

4. The date and time must be embedded on all surveillance recordings without significantly obscuring the picture. The date and time must be synchronized with any point-of-sale system.

5. Time is to be measured in accordance with the official United States time established by the National Institute of Standards and Technology and the U.S. Naval Observatory at: http://www.time.gov/timezone.cgi?Mountain/d/-7/java.

6. After the 40-day surveillance video retention schedule has lapsed, surveillance video recordings must be erased or destroyed prior to sale or transfer of the facility or business to another Licensee, or being discarded or disposed of for any other purpose. Surveillance video recordings may not be destroyed if the Licensee knows or should have known of a pending criminal, civil or administrative investigation or any other proceeding for which the recording may contain relevant information.

F. Other Records

1. All records applicable to the surveillance system shall be maintained on the Licensed Premises. At a minimum, Licensees shall maintain a map of the camera locations, direction of coverage, camera numbers, surveillance equipment maintenance activity log, user authorization list and operating instructions for the surveillance equipment.

2. A chronological point-of-sale transaction log must be made available to be used in conjunction with recorded video of those transactions.

Basis and Purpose – M 307

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish sanitary requirements for Medical Marijuana Businesses.

M 307 – Waste Disposal

A. All Applicable Laws Apply. Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product waste must be stored, secured and managed in accordance with all applicable state and local statutes, regulations, ordinances or other requirements.

B. Liquid Waste. Liquid waste from Medical Marijuana Businesses shall be disposed of in compliance all applicable federal, state and local laws, regulations, rules and other requirements.

C. Chemical, Dangerous and Hazardous Waste. Disposal of chemical, dangerous or hazardous waste must be conducted in a manner consistent with federal, state and local laws, regulations, rules or other requirements. This may include, but is not limited to, the disposal of all Pesticide or other chemicals used in the cultivation process, certain solvents or other chemicals used in the production of Medical Marijuana Concentrate or any Medical Marijuana soaked in a Flammable Solvent for purposes of producing a Medical Marijuana Concentrate.

D. Waste Must Be Made Unusable and Unrecognizable. Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product waste must be made unusable and Unrecognizable prior to leaving the Licensed Premises.

E. Methods to Make Waste Unusable and Unrecognizable. Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product waste shall be rendered unusable and Unrecognizable through one of the following methods:

1. Grinding or compacting and incorporating the marijuana waste with non-consumable, solid wastes listed below such that the resulting mixture is at least 50 percent non-marijuana waste, and such that the resulting mixture cannot easily be separated and sorted:

    a. Paper waste;

    b. Plastic waste;

    c. Cardboard waste;

    d. Food waste;

    e. Grease or other compostable oil waste;

    f. Bokashi, or other compost activators;

    g. Soil;

    h. Sawdust; and

    i. Other wastes approved by the State Licensing Authority that will render the Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product waste unusable and Unrecognizable as marijuana.

F. After Waste is Made Unusable and Unrecognizable. After the Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product waste is made unusable and Unrecognizable, then the rendered waste shall be:

1. Disposed of at a solid waste site and disposal facility that has a Certificate of Designation from the local governing body;

2. Deposited at a compost facility that has a Certificate of Designation from the Colorado Department of Public Health and Environment, if required; or

3. Composted on-site at a facility owned by the generator of the waste and operated in compliance with the Colorado Department of Public Health and Environment Regulations Pertaining to Solid Waste Sites and Facilities (6 CCR 1007-2, Part 1).

G. Proper Disposal of Waste. A Licensee shall not dispose of Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product waste in an unsecured waste receptacle not in possession and control of the Licensee.

H. Inventory Tracking Requirements

1. In addition to all other tracking requirements set forth in these rules, a Licensee shall utilize the Inventory Tracking System to ensure its post-harvest waste materials are identified, weighed and tracked while on the Licensed Premises until disposed of.

2. All Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product waste must be weighed before leaving any Medical Marijuana Business. A scale used to weigh Medical Marijuana waste prior to entry into the Inventory Tracking System shall be tested and approved in accordance with section 35-14-127, C.R.S. *See* Rule M 309 – Medical Marijuana Business: Inventory Tracking System.

3. A Licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of Marijuana. *See* Rule M 901 – Business Records Required.

4. A Licensee is required to maintain accurate and comprehensive records regarding any waste material produced through the trimming or pruning of a Medical Marijuana plant prior to harvest, which must include weighing and documenting all waste. Unless required by an Inventory Tracking System procedure, records of waste produced prior to harvest must be maintained on the Licensed Premises. All waste, whether produced prior to or subsequent to harvest, must be disposed of in accordance with this Rule and be made unusable and Unrecognizable.

Basis and Purpose – M 309

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-403(2), and 12-43.4-104(1)(a)(III) C.R.S. The purpose of this rule is to establish a system that will allow the State Licensing Authority and the industry to jointly track Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product from either seed or immature plant stage until the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product is sold to the patient or destroyed.

The Inventory Tracking System is a web-based tool coupled with RFID technology that allows both the Inventory Tracking System User and the State Licensing Authority the ability to identify and account for all Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. Through the use of RFID technology, an Optional Premises Cultivation facility will tag either the seed or immature

plant with an individualized number which will follow the Medical Marijuana through all phases of production and final sale to a patient. This will allow the State Licensing Authority and the Inventory Tracking System user the ability to monitor and track Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. The Inventory Tracking System will also provide a platform for the State Licensing Authority to exchange information and provide compliance notifications to the industry.

The State Licensing Authority finds it essential to regulate, monitor, and track all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product to eliminate diversion, inside and outside of the state, and to ensure that all marijuana grown, processed, sold and disposed of in the Medical Marijuana market is transparently accounted for. An existing Medical Marijuana Business must have an active and functional Inventory Tracking System account on or before December 31, 2013 or it may not excise the privileges of its license.

The State Licensing Authority will engage the industry and provide training opportunities and continue to evaluate the Inventory Tracking System to promote an effective means for this industry to account for and monitor its Medical Marijuana inventory.

M 309 – Medical Marijuana Business: Inventory Tracking System

A. Inventory Tracking System Required. A Medical Marijuana Business is required to use the Inventory Tracking System as the primary inventory tracking system of record. A Medical Marijuana Business without an Inventory Tracking System account that is activated and functional shall not operate or exercise any privileges of a license. Medical Marijuana Businesses converting to or adding a Retail Marijuana Establishment must follow the inventory transfer guidelines detailed in Rule R 309 (D) below.

B. Inventory Tracking System Access - Inventory Tracking System Administrator

1. Inventory Tracking System Administrator Required. A Medical Marijuana Business must have at least one individual Owner who is an Inventory Tracking System Administrator. A Medical Marijuana Business may also designate additional Owners and occupationally licensed employees to obtain Inventory Tracking System Administrator accounts.

2. Training for Inventory Tracking System Administrator Account. In order to obtain an Inventory Tracking System Administrator account, a person must attend and successfully complete all required Inventory Tracking System training. The Division may also require additional ongoing, continuing education for an individual to retain his or her Inventory Tracking System Administrator account.

C. Inventory Tracking System Access - Inventory Tracking System User Accounts. A Medical Marijuana Business may designate licensed Owners and employees who hold a valid Occupational License as an Inventory Tracking System User. A Medical Marijuana Business shall ensure that all Owners and Occupational Licensees who are granted Inventory Tracking System User account access for the purposes of conducting inventory tracking functions in the system are trained by Inventory Tracking System Administrators in the proper and lawful use of Inventory Tracking System.

D. Medical Marijuana Business License Conversions - Declaring Inventory Prior to Exercising Licensed Privileges as a Medical Marijuana Business

1. Medical Marijuana Inventory Transfer to Retail Marijuana Establishments.

a. Repealed.

b. Beginning July 1, 2016:

i. The only allowed Transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility.

ii. Each Optional Premises Cultivation Operation that is either converting to or adding a Retail Marijuana Cultivation Facility license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding.

iii. An Optional Premises Cultivation Operation must Transfer all relevant Medical Marijuana and Medical Marijuana Concentrate into the Retail Marijuana Cultivation Facility's Inventory Tracking System account and affirmatively declare those items as Retail Marijuana or Retail Marijuana Concentrate as appropriate.

iv. The declared Retail Marijuana or Retail Marijuana Concentrate that was subject to the one-time Transfer is subject to the excise tax upon the first Transfer from the Retail Marijuana Cultivation Facility to another Retail Marijuana Establishment.

v. All other Transfers are prohibited, including but not limited to Transfers from a Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer to any Retail Marijuana Establishment.

2. No Further Transfer Allowed. Once a Licensee has declared any portion of its Medical Marijuana inventory as Retail Marijuana, no further Transfers of inventory from Medical Marijuana to Retail Marijuana shall be allowed.

E. RFID Tags Required

1. Authorized Tags Required and Costs. Licensees are required to use RFID tags issued by a Division-approved vendor that is authorized to provision RFID tags for the Inventory Tracking System. Each licensee is responsible for the cost of all RFID tags and any associated vendor fees.

2. Use of RFID Tags Required. A Licensee is responsible to ensure its inventories are properly tagged where the Inventory Tracking System requires RFID tag use. A Medical Marijuana Business must ensure it has an adequate supply of RFID tags to properly tag Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product as required by the Inventory Tracking System. An RFID tag must be physically attached to every Medical Marijuana plant being cultivated that is greater than eight inches tall or eight inches wide. An RFID tag must be assigned to all Finished Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product. See also Rule M 801(G.5) – Required RFID Tags; Rule M 1001-1(F) – Shipping Containers.

3. Reuse of RFID Tags Prohibited. A Licensee shall not reuse any RFID tag that has already been affixed or assigned to any Finished Marijuana, Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

F. General Inventory Tracking System Use

1. Reconciliation with Inventory. All inventory tracking activities at a Medical Marijuana Business must be tracked through use of the Inventory Tracking System. A Licensee must reconcile all on-premises and in-transit Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product inventories each day in the Inventory Tracking System at the close of business.

2. Common Weights and Measures.

    a. A Medical Marijuana Business must utilize a standard of measurement that is supported by the Inventory Tracking System to track all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product.

    b. A scale used to weigh such product prior to entry into the Inventory Tracking System shall be tested and approved in accordance with section 35-14-127, C.R.S.

3. Inventory Tracking System Administrator and User Accounts – Security and Record

    a. A Medical Marijuana Business shall maintain an accurate and complete list of all Inventory Tracking System Administrators and Inventory Tracking System Users for each Licensed Premises. A Medical Marijuana Business shall update this list when a new Inventory Tracking System User is trained. A Medical Marijuana Business must train and authorize any new Inventory Tracking System Users before those Owners or employees may access Inventory Tracking System or input, modify, or delete any information in the Inventory Tracking System.

    b. A Medical Marijuana Business must cancel any Inventory Tracking System Administrators and Inventory Tracking System Users from their associated Inventory Tracking System accounts once any such individuals are no longer employed by the Licensee or at the Licensed Premises.

    c. A Medical Marijuana Business is accountable for all actions employees take while logged into the Inventory Tracking System or otherwise conducting Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product inventory tracking activities.

    d. Each individual user is also accountable for all of his or her actions while logged into the Inventory Tracking System or otherwise conducting Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product inventory tracking activities, and must maintain compliance with all relevant laws.

4. Secondary Software Systems Allowed

    a. Nothing in this rule prohibits a Medical Marijuana Business from using separate software applications to collect information to be used by the business including secondary inventory tracking or point of sale systems.

    b. A Licensee must ensure that all relevant Inventory Tracking System data is accurately transferred to and from the Inventory Tracking System for the purposes of reconciliations with any secondary systems.

    c. A Medical Marijuana Business must preserve original Inventory Tracking System data when transferred to and from a secondary application(s). Secondary software applications must use Inventory Tracking System data as the primary

source of data and must be compatible with updating to the Inventory Tracking System.

G. Conduct While Using Inventory Tracking System

1. Misstatements or Omissions Prohibited. A Medical Marijuana Business and its designated Inventory Tracking System Administrator(s) and Inventory Tracking System User(s) shall enter data into the Inventory Tracking System that fully and transparently accounts for all inventory tracking activities. Both the Medical Marijuana Business and the individuals using the Inventory Tracking System are responsible for the accuracy of all information entered into the Inventory Tracking System. Any misstatements or omissions may be considered a license violation affecting public safety.

2. Use of Another User's Login Prohibited. Individuals entering data into the Inventory Tracking System shall only use that individual's Inventory Tracking System account.

3. Loss of System Access. If at any point a Medical Marijuana Business loses access to the Inventory Tracking System for any reason, the Medical Marijuana Business must keep and maintain comprehensive records detailing all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product tracking inventory activities that were conducted during the loss of access. See Rule M 901 – Business Records Required. Once access is restored, all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana- Infused Product inventory tracking activities that occurred during the loss of access must be entered into the Inventory Tracking System. A Medical Marijuana Business must document when access to the system was lost and when it was restored. A Medical Marijuana Business shall not Transfer any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to another Medical Marijuana Business until such time as access is restored and all information is recorded into the Inventory Tracking System.

H. System Notifications

1. Compliance Notifications. A Medical Marijuana Business must monitor all compliance notifications from the Inventory Tracking System. The Licensee must resolve the issues detailed in the compliance notification in a timely fashion. Compliance notifications shall not be dismissed in the Inventory Tracking System until the Medical Marijuana Business resolves the compliance issues detailed in the notification.

2. Informational Notifications. A Medical Marijuana Business must take appropriate action in response to informational notifications received through the Inventory Tracking System, including but not limited to notifications related to RFID billing, enforcement alerts, and other pertinent information.

I. Lawful Activity Required. Proper use of the Inventory Tracking System does not relieve a Licensee of its responsibility to maintain compliance with all laws, rules, and other requirements at all times.

J. Inventory Tracking System Procedures Must Be Followed. A Medical Marijuana Business must utilize the Inventory Tracking System in conformance with these rules and Inventory Tracking System procedures, including but not limited to:

1. Properly indicating the creation of a Harvest Batch and/or Production Batch including the assigned Harvest Batch and/or Production Batch Number;

2. Accurately identifying the cultivation rooms and location of each plant within those rooms on the Licensed Premises;

3. Accurately identifying when inventory is no longer on the Licensed Premises;

4. Properly indicating that a Test Batch is being used as part of achieving process validation;

5. Accurately indicating the Inventory Tracking System category for all Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product; and

6. Accurately including a note explaining the reason for any destruction of Medical Marijuana, Medical Marijuana Concentrate and/or Medical Marijuana-Infused Product, and reason for any adjustment of weights to Inventory Tracking System packages.

M 400 Series – Medical Marijuana Centers

Basis and Purpose – M 401

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F),12-43.3-310(7), 12-43.3-310(4), 12-43.3-402 and 12-43.3-406, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana Center Licensee to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

M 401 – Medical Marijuana Center: License Privileges

A. Privileges Granted. A Medical Marijuana Center shall only exercise those privileges granted to it by the State Licensing Authority.

B. Licensed Premises. To the extent authorized by Rule M 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation, a Medical Marijuana Center may share a location with a commonly-owned Retail Marijuana Store. However, a separate license is required for each specific business or business entity, regardless of geographical location.

C. Authorized Sources of Medical Marijuana. A Medical Marijuana Center may only Transfer Medical Marijuana that it has purchased from another Medical Marijuana Center or that the Medical Marijuana Center has cultivated itself, after first obtaining an Optional Premises Cultivation Operation License. See Rule M 501 – Optional Premises Cultivation Operation: License Privileges.

D. Authorized Sources of Medical Marijuana-Infused Product Inventory. A Medical Marijuana Center may Transfer Medical Marijuana-Infused Product that it has purchased from a Medical Marijuana-Infused Products Manufacturer, so long as each product are pre-packaged and labeled upon purchase from the manufacturer.

E. Samples Provided for Testing.

1. Repealed.

1.5. A Medical Marijuana Center may provide Samples of its products to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Center shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.

F. Authorized On-Premises Storage. A Medical Marijuana Center is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.

G. Authorized Marijuana Transport. A Medical Marijuana Center is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product so long as the place where transportation orders are taken and delivered is a licensed Medical Marijuana Business. Nothing in this Rule prevents a Medical Marijuana Center from transporting its own Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product.

Basis and Purpose – M 402

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), 12-43.3-310(4), 12-43.3-402, and 12-43.3-403, C.R.S. The purpose of this rule is to establish that a Medical Marijuana Center can only grow Medical Marijuana in its Optional Premises Cultivation Operation for a patient that has designated that Medical Marijuana Center as being his or her primary center. The rule also helps to ensure that Medical Marijuana plants designated to a particular patient are only being grown at one Medical Marijuana Center.

M 402 – Registration of a Primary Medical Marijuana Center

A. Patient Designation Required. A Medical Marijuana Center may possess in the aggregate, only the amount of Medical Marijuana and number of Medical Marijuana plants permitted by Rule M 403(A.5) for each patient who has designated the Medical Marijuana Center as being his or her primary center. A patient's designation of a Medical Marijuana Center as his or her primary Medical Marijuana Center in accordance with these Rules establishes the Medical Marijuana Center registration requirements set forth in sections 12-43.3-901(4)(e), and 25-1.5-106(8)(f), C.R.S.

B. Change Only Allowed Every 30 Days. A Medical Marijuana Center shall not register a patient as being the patient's primary center if the patient has designated another Medical Marijuana Center as his or her primary center in the preceding 30 days. The Medical Marijuana Center and its employees must require a patient to sign in writing that he or she has not designated another Medical Marijuana Center as his or her primary center before growing Medical Marijuana plants on behalf of the patient.

C. Notification to Former Medical Marijuana Center. A Medical Marijuana Center must maintain a copy of a written or electronic notification that it provided to a patient's former primary Medical Marijuana Center advising that the Medical Marijuana Center has been designated as the patient's new primary Medical Marijuana Center.

D. Documents Required. The new primary Medical Marijuana Center shall maintain written authorization from the patient, any relative plant count waiver to support the number of plants designated for that patient, a copy of the patient's registry card, and a copy of the patient's proof of identification. *See also* Rule M 901 – Business Records Required.

E. Violation of Public Safety. Notwithstanding the provisions in Rule M 402 (B), it may be considered a violation of public safety for a Medical Marijuana Center and its employees to become a patient's primary center when the patient already had designated one or more other Medical Marijuana Centers as his or her primary center.

Basis and Purpose – M 403

The statutory authority for this includes but is not limited to sections 12-43.3-103(2)(b), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), 12-43.3-310(4), 12-43.4-401(4), 12-43.3-402, and 12-43.3-406, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 14(4). The purpose of this rule is to clarify those acts that are prohibited, or limited in some fashion, by a licensed Medical Marijuana Center. This rule also restricts the amount of its inventory a Medical Marijuana Center may sell to other Medical Marijuana Businesses to 30 percent.

The quantity limitations on sales provision is intended to inform stakeholders in order to aid in compliance with a patient's lawful Medical Marijuana limit. Clarifying the quantity limitations on sales provides Medical Marijuana Centers and their employees with necessary information to avoid being complicit in a patient acquiring more Medical Marijuana than is lawful under the Colorado Constitution pursuant to Article XVIII, Subsection 14(4).

M 403 – Medical Marijuana Sales: General Limitations or Prohibited Acts

A. 30 Percent Rule. Pursuant to section 12-43.3-402(4), C.R.S., a Medical Marijuana Center may accept Transfers of not more than 30 percent of its total on-hand medical marijuana inventory from another licensed Medical Marijuana Center in Colorado. A Medical Marijuana Center may Transfer no more than thirty percent of its total on-hand Medical Marijuana inventory to another Medical Marijuana Center.

1. Total on-hand inventory as used in section 12-43.3-402(4), C.R.S., means the total amount of Medical Marijuana that a Medical Marijuana Center received from its dedicated Optional Premises Cultivation Operation or any other Medical Marijuana Center in the preceding 12 months.

2. A Medical Marijuana Center may apply for a temporary waiver from the requirements set forth in this Rule and section 12-43.3-402(4), C.R.S. under the following circumstances:

    a. A Medical Marijuana Center that suffers a catastrophic event related to its total on-hand inventory; examples of a catastrophic event include, but are not limited to: blight, crop failure, crop contamination, or natural disasters; or

    b. To a new Medical Marijuana Center Licensee for a period not to exceed 90 days from the commencement of the first cultivation activities.

A.5 Possession Limits. Possession limits set forth in this Rule refer to the maximum total quantity possessed by the Medical Marijuana Center and its designated Optional Premises Cultivation Operation collectively. For purposes of section 12-43.3-901(4)(e), C.R.S., a Medical Marijuana Center and its designated Optional Premises Cultivation Operation may possess six (6) Medical Marijuana plants and two (2) ounces of Finished Marijuana for each patient who has registered the Medical Marijuana Center as his or her primary Medical Marijuana Center.

1. Subject to the requirement in Paragraph A.5(2) of this Rule, a Medical Marijuana Center and its designated Optional Premises Cultivation Operation may exceed the six (6) Medical Marijuana plant and two (2) ounces of Finished Marijuana per-patient limits for patients registered with the Medical Marijuana Center who are authorized by the registered patient's physician to exceed the six (6) Medical Marijuana plant and two (2) ounces of Medical Marijuana limits.

2. A Medical Marijuana Center and its designated Optional Premises Cultivation Operation shall not exceed the six (6) Medical Marijuana plant and two (2) ounces of Finished Marijuana per-patient limits unless it obtains and maintains documentation from the

registered patient's physician authorizing the patient to exceed the six (6) Medical Marijuana plant and two (2) ounces of Medical Marijuana limits.

3. Under no circumstance shall a Medical Marijuana Center and its designated Optional Premises Cultivation Operation possess Medical Marijuana plants and Finished Marijuana in excess of the total amount of Medical Marijuana plants and Finished Marijuana that its registered patients are authorized to possess.

B. Medical Marijuana-Infused Products Manufacturers. A Medical Marijuana Center may also contract for the manufacture of Medical Marijuana-Infused Product with Medical Marijuana-Infused Product Licensees utilizing a contract as provided for in Rule M 602 – Medical Marijuana-Infused Products Manufacturer: General or Prohibited Acts (Infused Product Contracts). Medical Marijuana distributed to a Medical Marijuana-Infused Products Manufacturer by a Medical Marijuana Center pursuant to such a contract for use solely in Medical Marijuana-Infused Product(s) that are returned to the contracting Medical Marijuana Center shall not be included for purposes of determining compliance with subsection A.

C. Consumption Prohibited. Licensees shall not permit the consumption of marijuana or a marijuana product on the Licensed Premises.

D. Quantity Limitations On Transfers. During a single transaction to a patient, a Medical Marijuana Center and its employees are prohibited from Transferring:

a. More than two ounces of Medical Marijuana unless the patient has designated the Medical Marijuana Center as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than two ounces of Medical Marijuana;.

b. More than the patient's extended ounce count to a patient who designated the Medical Marijuana Center as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than two ounces of Medical Marijuana;

c. More than six Immature plants unless the patient has designated the Medical Marijuana Center as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six plants;

d. More than half of the patient's extended plant count to a patient who has designated the Medical Marijuana Center as his or her primary center and supplied it with documentation from the patient's physician allowing the patient more than six plants.

D.5 For purposes of Rule M 403(D), a single transaction to a patient includes multiple sales to the same patient during the same business day where the Medical Marijuana Center employee knows or reasonably should know that such sale would result in the patient possessing more than the quantities of Medical Marijuana or Immature plants set forth above. In determining the imposition of any penalty for violation of this Rule 403(D), the State Licensing Authority will consider any mitigating and aggravating factors set forth in Rule M 1307(C).

E. Licensees May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a patient.

F. Storage and Display Limitations. A Medical Marijuana Center shall not display Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product outside of a designated Restricted Access Area or in a manner in which Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product can be seen from outside the Licensed

Premises. Storage of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product shall otherwise be maintained in Limited Access Areas or Restricted Access Area.

G. Transfer of Expired Product Prohibited. A Medical Marijuana Center shall not Transfer any expired Medical Marijuana-Infused Product.

G.1 Transfer Restrictions. A Medical Marijuana Center shall not sell or give away Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy, or receive complimentary Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.

G.2 Performance-Based Sales Incentives Prohibited. A Medical Marijuana Center shall not compensate its employees using performance-based sales incentives. Performance-based incentives that are not sales-based are acceptable. Examples of performance-based incentives that are not sales-based include recognition for providing quality information to consumers, or the duration of the employee's employment with the Medical Marijuana Center.

G.3 Edibles Prohibited that are Shaped like a Human, Animal, or Fruit. This paragraph (G.3) is effective beginning October 1, 2017.

1. The Transfer of Edible Medical Marijuana-Infused Product in the following shapes is prohibited:

    a. The distinct shape of a human, animal, or fruit; or

    b. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.

2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Medical Marijuana Business. Nothing in this subparagraph (G.3)(2) alters or eliminates a Licensee's obligation to comply with the requirements of Rule M 1001.5 – Labeling and Packaging Requirements: General Applicability or Rule M 1000-1 Series – Packaging, Labeling, and Product Safety.

3. Edible Medical Marijuana-Infused Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and

4. Edible Medical Marijuana-Infused Products that are manufactured in the shape of a marijuana leaf are permissible.

H. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose – M 405

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), and 12-43.3-402(5), C.R.S. The Medical Code requires Medical Marijuana Center employees to verify that the purchaser has a valid registration card issued pursuant to section 25-1.5-106, C.R.S., and a valid picture identification card that matches the name on the registration card. Accordingly, this rule was adopted to explain exactly what types of picture identification cards can be accepted. Not only will this rule alleviate any confusion on the part of Medical Marijuana Center employees, but it will help reduce the amount of fraudulent transactions, thereby helping to maintain the integrity of Colorado's Medical Marijuana Businesses.

M 405 – Acceptable Forms of Identification for Medical Marijuana Sales

A. When Sales Allowed. Medical Marijuana Centers shall only Transfer Medical Marijuana to any patient or caregiver permitted to deliver Medical Marijuana to homebound patients as permitted by section 25-1.5-106(9)(e), C.R.S., if the patient or caregiver can produce:

1. A valid patient registry card and adequate, currently valid proof of identification; or

2. A copy of a current and complete new application for the Medical Marijuana registry that is documented by a certified mail return receipt as having been submitted to the Colorado Department of Public Health and Environment within the preceding thirty-five days and adequate, currently valid proof of identification.

B. Acceptable Forms of Identification. As long as it contains a picture and date of birth, the kind and type of identification deemed adequate shall be limited to the following:

1. An operator's, chauffeur's or similar type driver's license, issued by any state within the United States, any U.S. Territory;

2. An identification card, issued by any state for the purpose of proof of age using requirements similar to those in sections 42-2-302 and 42-2-303, C.R.S.;

3. A United States military identification card;

4. A passport; or

5. An enrollment card issued by the governing authority of a federally recognized Indian tribe located in the state of Colorado, if the enrollment card incorporates proof of age requirements similar to sections 42-2-302 and 42-2-303, C.R.S.

C. Physical Inspection Required. A Licensee must physically view and inspect the patient or caregiver's registry card and proof of identification to confirm the information contained on the documents and also to judge the authenticity of the documents presented.

Basis and Purpose – M 406

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XX), and 12-43.3-402(1)(b), C.R.S. The purpose of this rule is to require all Medical Marijuana-Centers to track all inventory from the point it is received to the point-of-sale or Transfer to another Medical Marijuana Center.

M 406 – Medical Marijuana Center: Inventory Tracking System

A. Minimum Tracking Requirement. Medical Marijuana Centers must use the Inventory Tracking System to ensure its Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Products are identified and tracked from the point of Transfer to or from another Medical Marijuana Business through the point-of-sale. See Rule M 309 – Inventory Tracking System. Medical Marijuana Center: Inventory Tracking System. The Medical Marijuana Center must have the ability to reconcile its inventory records with the Inventory Tracking System and the associated transaction history and sale receipts. See also Rule M 901 – Business Records Required.

1. A Medical Marijuana Center is prohibited from accepting any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Products without receiving a valid transport manifest generated from the Inventory Tracking System.

2. A Medical Marijuana Center must immediately input all Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product delivered to its Licensed Premises, accounting for all RFID tags, into the Inventory Tracking System at the time of delivery to the Medical Marijuana Center.

3. A Medical Marijuana Center must immediately account for all Medical Marijuana Transferred to another Medical Marijuana Center in the Inventory Tracking System.

4. A Medical Marijuana Center must reconcile transactions from their point of sale processes and inventory to the Inventory Tracking System at the close of business each day.

Basis and Purpose – M 407

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish minimum health and safety regulations for Medical Marijuana Centers. It sets forth general standards and basic sanitary requirements for Medical Marijuana Centers. It covers the physical premises where the products are made as well as the individuals handling the products. This rule also authorizes the State Licensing Authority to require an independent consultant conduct a health and sanitary audit of a Medical Marijuana Center. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Business's refusal to cooperate or pay for the audit. The State Licensing Authority modeled this rule after those adopted by the Colorado Department of Public Health and Environment. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Centers.

M 407 - Health and Safety Regulations: Medical Marijuana Center

A. Local Safety Inspections. Licensees may be subject to inspection of the Medical Marijuana Center by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local jurisdiction restrictions related to Medical Marijuana. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

B. General Sanitary Requirements. The Licensee shall take all reasonable measures and precautions to ensure the following:

1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in contamination until the condition is corrected;

2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

3. That all persons working in direct contact with Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:

a. Maintaining adequate personal cleanliness;

b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated; and

c. Refraining from having direct contact with Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

4. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product are exposed;

5. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and each is kept clean and in good repair;

6. That there is adequate lighting in all areas where Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product are stored or sold, and where equipment or utensils are cleaned;

7. That the Licensee provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

8. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;

9. That toxic cleaning compounds, sanitizing agents, and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product and in a manner that is in accordance with any applicable local, state or federal law, rule, regulation or ordinance;

10. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles;

11. That each Medical Marijuana Center provides its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and

12. That Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms are held in a manner that prevents the growth of these microorganisms.

C. Independent Health and Sanitary Audit

1. State Licensing Authority May Require A Health and Sanitary Audit

a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Medical Marijuana Center

to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Medical Marijuana Center is in compliance with the requirements set forth in this Rule and other applicable health, sanitary or food handling laws, rules and regulations.

b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Medical Marijuana Center. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

c. The Medical Marijuana Center will be responsible for all costs associated with the independent health and sanitary audit.

2. When Independent Health and Sanitary Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:

a. The Division has reasonable grounds to believe that the Medical Marijuana Center is in violation of one or more of the requirements set forth in this Rule or other applicable public health or sanitary laws, rules or regulations; or

b. The Division has reasonable grounds to believe that the Medical Marijuana Center was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

3. Compliance Required. A Medical Marijuana Center must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this Rule.

4. Suspension of Operations

a. If the State Licensing Authority has objective and reasonable grounds to believe and finds upon reasonable ascertainment of the underlying facts that the public health, safety or welfare imperatively requires emergency action and incorporates such findings into its order, it may order summary suspension of the Medical Marijuana Center's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

b. Prior to or following the issuance of such an order, the Medical Marijuana Center may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.

i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

ii. If an agreement to suspend operations is reached, then the Medical Marijuana Center may continue to care for its inventory and conduct any necessary internal business operations but it may not sell any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused

Product to a patient or other Medical Marijuana Business during the period of time specified in the agreement.

5. Repealed.

D. Contaminated Product. A Medical Marijuana Center shall not accept or Transfer to any Person any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product that has failed required testing pursuant to Rule M 1501 or Rule M 1503, unless otherwise permitted in these rules. If, despite the prohibitions in these rules, another Medical Marijuana Business Transfers to the Medical Marijuana Center any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product that has failed or subsequently fails required testing pursuant to Rule M 1501 or Rule M 1503, the Medical Marijuana Center shall assure that all Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Products that failed required testing are safely disposed of in accordance with Rule R 307.

E. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose - M 408

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X),12-43.3-202(2)(a)(XIII), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-1101, and 12-43.3-1102, C.R.S. The purpose of this rule is to establish minimum standards for responsible vendor programs that provide training to personnel at Medical Marijuana Centers seeking designation as a "responsible vendor." It sets forth general standards and basic requirements for responsible vendor programs. This rule also establishes the timeframe for new staff to complete a responsible vendor program and the requirements for recertification. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Centers.

M 408 - Medical Marijuana Center: Responsible Vendor Program

A. General Standards.

1. To be designated a "responsible vendor" of Medical Marijuana, Medical Marijuana-Infused Product and Medical Marijuana Concentrate at any licensed Medical Marijuana Center, a Medical Marijuana Center licensee shall comply with this Rule.

2. To be designated a "responsible vendor" all Owners, managers and employees involved in the handling and Transfer of Medical Marijuana, Medical Marijuana Infused-Product or Medical Marijuana Concentrate shall attend and successfully complete a responsible vendor program.

3. Once a licensee is designated a "responsible vendor," all new employees involved in the handling and Transfer of Medical Marijuana, Medical Marijuana Infused-Product or Medical Marijuana Concentrate shall successfully complete the training described in this rule within 90 days of hire.

4. After initial successful completion of a responsible vendor program, each Owner, manager and employee of a Medical Marijuana Center shall successfully complete the program once every two years thereafter to maintain designation as a "responsible vendor."

B. Certification Training Program Standards.

1. No owner or employee of a responsible vendor program shall have an interest in a licensed Medical Marijuana Business or Retail Marijuana Establishment.

2. Program providers shall submit their programs to the Division for approval as a responsible vendor program.

3. Program providers shall submit their programs for approval every two years in order to maintain designation as a responsible vendor program.

4. The program shall include at least two hours of instruction time.

5. The program shall be taught in a real-time, interactive classroom setting where the instructor is able to verify the identification of each individual attending the program and certify completion of the program by the individual identified.

6. The program provider shall maintain its training records at its principal place of business during the applicable year and for the following three years. The provider shall make the records available for inspection by the licensing authority upon request during normal business hours.

7. The program shall provide written documentation of attendance and successful passage of a test on the knowledge of the required curriculum for each attendee.

    a. Attendees who can speak and write English must successfully pass a written test with a score of 70% or better.

    b. Attendees who cannot speak or write English may be offered a verbal test, provided that the same questions are given as are on the written test and the results of the verbal test are documented with a passing score of 70% or better.

8. Program providers shall solicit effectiveness evaluations from individuals who have completed their program.

C. Certification Training Class Core Curriculum.

1. Discussion concerning marijuana's effect on the human body. Training shall include:

    a. Marijuana's physical effects based on type of marijuana product;

    b. The amount of time to feel impairment;

    c. Visible signs of impairment; and

    d. Recognizing the signs of impairment.

2. Sales to minors. Training shall cover all pertinent Colorado statutes, rules, and regulations. .

3. Quantity limitations on Transfers to patients. Training shall cover all pertinent Colorado statutes, rules, and regulations.

4. Acceptable forms of Identification. Training shall include:

    a. How to check identification;

b. Spotting false identification;

c. Patient Registry Cards issued by the Colorado Department of Public Health and Environment and equivalent patient verification documents;

d. Provisions for confiscating fraudulent identifications; and

e. Common mistakes made in verification.

5. Other key state laws and rules affecting owners, managers, and employees. Training shall include:

a. Local and state licensing and enforcement;

b. Compliance with all Inventory Tracking System regulations;

c. Administrative and criminal liability;

d. License sanctions and court sanctions;

e. Waste disposal;

f. Health and safety standards;

g. Patrons prohibited from bringing marijuana onto licensed premises;

h. Permitted hours of sale;

i. Conduct of establishment;

j. Permitting inspections by state and local licensing and enforcement authorities;

k. Licensee responsible for activities occurring within licensed premises;

l. Maintenance of records;

m. Privacy issues; and

n. Prohibited purchases.

500 Series – Medical Marijuana Optional Premises Cultivation Operation: License Privileges

Basis and Purpose – M 501

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.4-401(4), 12-43.3-310, 12-43.4-402, 12-43.3-403, 12-43.3-404, and 12-43.4-406, C.R.S. The purpose of this rule is to establish that it is unlawful for an Optional Premises Cultivation Operation to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

M 501 – Medical Marijuana Optional Premises Cultivation Operation: License Privileges

A. Privileges Granted. A Medical Marijuana Optional Premises Cultivation Operation shall only exercise those privileges granted to it by the State Licensing Authority.

B. Licensed Premises. To the extent authorized by Rule M 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation, a Medical Marijuana Optional Premises Cultivation Facility may share a location with a commonly-owned Retail Marijuana Cultivation Facility. However, a separate license is required for each specific business entity regardless of geographical location.

C. Cultivation of Medical Marijuana Authorized. A Medical Marijuana Optional Premises Cultivation Operation may Propagate, cultivate, harvest, prepare, cure, package, store, and label Medical Marijuana, whether in concentrated form or otherwise.

D. Authorized Transfers. A Medical Marijuana Optional Premises Cultivation Operation may only Transfer Medical Marijuana and Water-Based Medical Marijuana Concentrate to the Medical Marijuana Center or Medical Marijuana Infused Products Manufacturer it is designated to pursuant to section 12-43.3-403, C.R.S.

1. A Medical Marijuana Optional Premises Cultivation Operation is also authorized to Transfer Medical Marijuana to a Licensed Research Business pursuant to section 12-43.3-408, C.R.S., a Medical Research Facility pursuant to section 25-1.5-106.5, C.R.S., or Pesticide Manufacturer pursuant to section 12-43.3-202(1)(h)(II), C.R.S. Until such Transfer, any Finished Marijuana at the Optional Premises Cultivation Operation shall count against the possession limits for the Medical Marijuana Center the Optional Premises Cultivation Operation is designated to pursuant to section 12-43.3-403, C.R.S. See Rule M 403(A.5).

2. An Optional Premises Cultivation shall not Transfer Flowering plants or Vegetative plants to any Person except as authorized pursuant to Rule M 801.

E. Packaging Processed Medical Marijuana. Processed Medical Marijuana plants shall be packaged in units of ten pounds or less and labeled pursuant to Rule M 1002 - Labeling Requirements: General Requirements or the Rule M 1000-1 Series – Labeling, Packaging, and Product Safety, and securely sealed in a tamper-evident manner.

F. Authorized Marijuana Transport. A Medical Marijuana Optional Premises Cultivation is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana so long as the place where transportation orders are taken is a Medical Marijuana Business and the transportation order is delivered to a licensed Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana Optional Premises Cultivation from transporting its own Medical Marijuana.

G. Performance-Based Incentives. A Medical Marijuana Optional Premises Cultivation may compensate its employees using performance-based incentives.

H. Authorized Sources of Medical Marijuana Seeds and Immature Plants. A Medical Marijuana Optional Premises Cultivation Operation shall only obtain Medical Marijuana seeds or Immature Plants from its own Medical Marijuana or properly transferred from another Medical Marijuana Business pursuant to the inventory tracking requirements in this Rule, and as long as there is first a documented point-of-sale transaction at that Optional Premises Cultivation Operation's designated Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer.

Basis and Purpose – M 502

The statutory authority for this rule includes but is not limited to sections 12-43.3-103(2)(b), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), and 12-43.3-202(2)(a)(XX), 12-43.3-310, 12-43.3-402, 12-43.3-403, 12-43.3-406, 12-43.3-201, C.R.S. The purpose of this rule is to clarify what activity is or is not allowed at an Optional Premises Cultivation Operation.

M 502 – Medical Marijuana Optional Premises Cultivation Operation: General Limitations or Prohibited Acts

A. Transfer Restriction. An Optional Premises Cultivation Operation may only Transfer Medical Marijuana to its commonly-owned Medical Marijuana Center or to a Medical Marijuana-Infused Products Manufacturer.

B. Packaging and Labeling Standards Required. An Optional Premises Cultivation Operation is prohibited from Transferring Medical Marijuana and Medical Marijuana Concentrate that is not packaged and labeled in accordance with these rules. See Rules M 1001.5 *et. seq.* and the Rule M 1000-1 Series– Labeling, Packaging, and Product Safety.

C. Transfer to Patient Prohibited. An Optional Premises Cultivation Operation is prohibited from Transferring Medical Marijuana to a patient.

D. Consumption Prohibited. An Optional Premises Cultivation Operation shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.

E. Sales and Gift to Transporters Prohibited. A Medical Marijuana Optional Premises Cultivation shall not sell or give away Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana, Medical Marijuana Concentrate, or Medical-Marijuana Infused Product from a Medical Marijuana Transporter.

F. Inventory Limit. An Optional Premises Cultivation Operation shall not possess more plants than its commonly-owned Medical Marijuana Center is authorized to possess. See Rule M 403(A.5) – Medical Marijuana Sales: General Limitations or Prohibited Acts.

Basis and Purpose – M 503

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XX), and 12-43.3-403(3), C.R.S. The purpose of this rule is to eliminate diversion of Medical Marijuana.

M 503 – Medical Marijuana Optional Premises Cultivation Operation: Inventory Tracking System

A. Minimum Tracking Requirement. An Optional Premises Cultivation Operation must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point Medical Marijuana is Propagated from seed or cutting to the point when it is delivered to a Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. *See* Rule M 309, Medical Marijuana Business: Inventory Tracking System. An Optional Premises Cultivation Operation must have the ability to reconcile its inventory records generated from the Inventory Tracking System and the associated transaction history and sale receipts. *See* Rule M 901 – Business Records Required.

1. An Optional Premises Cultivation Operation is prohibited from accepting any Medical Marijuana without receiving a valid transport manifest generated from the Inventory Tracking System.

2. An Optional Premises Cultivation Operation must immediately input all Medical Marijuana delivered to its Licensed Premises and account for all RFID tags into the Inventory Tracking System at the time of delivery to the Optional Premises Cultivation Operation.

3. An Optional Premises Cultivation Operation must reconcile its transaction history and on-hand Medical Marijuana to the Inventory Tracking System at the close of business each day.

Basis and Purpose – M 504

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish minimum health and safety regulations for Optional Premises Cultivation Operations. The rule prohibits an Optional Premises Cultivation Operation from treating or otherwise adulterating Medical Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell. This rule also authorizes the State Licensing Authority to require an independent consultant conduct an independent health and sanitary audit of an Optional Premises Cultivation Operation. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Business's refusal to cooperate or pay for the audit. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses.

M 504 – Optional Premises Cultivation Operation: Health and Safety Regulations

A. Local Safety Inspections. An Optional Premises Cultivation Operation may be subject to inspection of its Licensed Premises by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local jurisdiction restrictions related to Medical Marijuana or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

B. General Sanitary Requirements. An Optional Premises Cultivation Operation shall take all reasonable measures and precautions to ensure the following:

1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with Medical Marijuana shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;

2. That all persons working in direct contact with Medical Marijuana shall conform to hygienic practices while on duty, including but not limited to:

a. Maintaining adequate personal cleanliness;

b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated;

c. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices; and

d. Refraining from having direct contact with Medical Marijuana if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or

any other abnormal source of microbial contamination, until such condition is corrected.

3. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Medical Marijuana is exposed;

4. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;

5. That there is adequate lighting in all areas where Medical Marijuana is stored and where equipment or utensils are cleaned;

6. That the Licensee provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

7. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;

8. That toxic cleaning compounds, sanitizing agents, and solvents shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana or Medical Marijuana Concentrate, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. All Pesticides must be stored and disposed of in accordance with the information provided on the product's label;

9. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana or Medical Marijuana Concentrate shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in an Optional Premises Cultivation Operation and used in accordance with labeled instructions;

10. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs. Reclaimed water may also be used only for the cultivation of Medical Marijuana to the extent authorized under the Reclaimed Water Control Regulations (5 CCR 1002-84), and subject to approval of the Water Quality Control Division of the Colorado Department of Public Health and Environment and the local water provider;

11. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable water, reclaimed water, and waste water lines;

12. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Medical Marijuana, Medical Marijuana or Concentrate shall be conducted in accordance with adequate sanitation principles;

13. That each Optional Premises Cultivation Operation shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and

14. That Medical Marijuana that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.

C. Pesticide Application. An Optional Premises Cultivation Operation may only use Pesticide in accordance with the "Pesticide Act" sections 35-9-101 et seq., C.R.S., the "Pesticides Applicators' Act," sections 35-10-101 et seq., C.R.S., and all other applicable federal, state, and local laws, statutes, rules and regulations. This includes, but shall not be limited to, the prohibition on detaching, altering, defacing or destroying, in whole or in part, any label on any Pesticide. The Colorado Department of Agriculture's determination that the Licensee used any quantity of a Pesticide that would constitute a violation of the Pesticide Act or the Pesticide Applicators' Act shall constitute *prima facie* evidence of a violation of this Rule.

D. Application of Other Agricultural Chemicals. An Optional Premises Cultivation Operation may only use agricultural chemicals, other than Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules and regulations.

E. Required Documentation

1. Standard Operating Procedures. An Optional Premises Cultivation Operation must establish written standard operating procedures for the cultivation, harvesting, drying, curing, packaging, storing, and sampling of Medical Marijuana, and the processing, packaging, storing, and sampling of Medical Marijuana Concentrate. The standard operating procedures must also include when, and the manner in which, all Pesticide and other agricultural chemicals are to be applied during its cultivation process. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Optional Premises Cultivation Operation.

2. Material Change. If an Optional Premises Cultivation Operation makes a Material Change to its cultivation procedures, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

3. Safety Data Sheet. An Optional Premises Cultivation Operation must obtain a safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. An Optional Premises Cultivation Operation must maintain a current copy of the safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.

4. Labels of Pesticide and Other Agricultural Chemicals. An Optional Premises Cultivation Operation must have the original label or a copy thereof at its Licensed Premises for all Pesticide and other agricultural chemicals used during its cultivation process.

5. Pesticide Application Documentation. An Optional Premises Cultivation Operation that applies any Pesticide or other agricultural chemical to any portion of a Medical Marijuana plant, water or feed used during cultivation or generally within the Licensed Premises must document, and maintain a record on its Licensed Premises of, the following information:

a. The name, signature and Occupational License number of the individual who applied the Pesticide or other agricultural chemical;

b. Applicator certification number if the applicator is licensed through the Department of Agriculture in accordance with the "Pesticides Applicators' Act," sections 35-10-101 et seq., C.R.S.;

c. The date and time of the application;

d. The EPA registration number of the Pesticide or CAS number of any other agricultural chemical(s) applied;

e. Any of the active ingredients of the Pesticide or other agricultural chemical(s) applied;

f. Brand name and product name of the Pesticide or other agricultural chemical(s) applied;

g. The restricted entry interval from the product label of any Pesticide or other agricultural chemical(s) applied;

h. The RFID tag number of the Medical Marijuana plant(s) that the Pesticide or other agricultural chemical(s) was applied to or if applied to all plants throughout the Licensed Premises, a statement to that effect; and

i. The total amount of each Pesticide or other agricultural chemical applied.

F. Prohibited Chemicals. The following chemicals are prohibited and shall not be used in Medical Marijuana cultivation. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this Rule. Additionally, possession of Medical Marijuana or Medical Marijuana Concentrate on which any of the following chemicals is detected shall constitute a violation of this Rule.

1. Any Pesticide the use of which would constitute a violation of the Pesticide Act, section 35-9-101 *et seq.*, C.R.S., the Pesticide Applicators' Act, section 35-10-101 et seq., C.R.S., or the rules and regulations pursuant thereto.

2. Other chemicals (listed by chemical name and CAS Registry Number (or EDF Substance ID)):

ALDRIN

309-00-2

ARSENIC OXIDE (3)

1327-53-3

ASBESTOS (FRIABLE)

1332-21-4

AZODRIN

6923-22-4

1,4-BENZOQUINONE, 2,3,5,6-TETRACHLORO-

118-75-2

BINAPACRYL

485-31-4

2,3,4,5-BIS (2-BUTENYLENE) TETRAHYDROFURFURAL

126-15-8

BROMOXYNIL BUTYRATE

EDF-186

CADMIUM COMPOUNDS

CAE750

CALCIUM ARSENATE [2ASH3O4.2CA]

7778-44-1

CAMPHECHLOR

8001-35-2

CAPTAFOL

2425-06-1

CARBOFURAN

1563-66-2

CARBON TETRACHLORIDE

56-23-5

CHLORDANE

57-74-9

CHLORDECONE (KEPONE)

143-50-0

CHLORDIMEFORM

6164-98-3

CHLOROBENZILATE

510-15-6

CHLOROMETHOXYPROPYLMERCURIC ACETATE [CPMA] EDF-

183

COPPER ARSENATE

10103-61-4

2,4-D, ISOOCTYL ESTER

25168-26-7

DAMINOZIDE

1596-84-5

DDD

72-54-8

DDT

50-29-3

DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS] EDF-

187

1,2-DIBROMO-3-CHLOROPROPANE (DBCP)

96-12-8

1,2-DIBROMOETHANE

106-93-4

1,2-DICHLOROETHANE

107-06-2

DIELDRIN

60-57-1

4,6-DINITRO-O-CRESOL

534-52-1

DINITROBUTYL PHENOL

88-85-7

ENDRIN

72-20-8

EPN

2104-64-5

ETHYLENE OXIDE

75-21-8

FLUOROACETAMIDE

640-19-7

GAMMA-LINDANE

58-89-9

HEPTACHLOR

76-44-8

HEXACHLOROBENZENE

118-74-1

1,2,3,4,5,6-HEXACHLOROCYCLOHEXANE (MIXTURE OF ISOMERS)

608-73-1

1,3-HEXANEDIOL, 2-ETHYL-

94-96-2

LEAD ARSENATE

7784-40-9

LEPTOPHOS

21609-90-5

MERCURY

7439-97-6

METHAMIDOPHOS

10265-92-6

METHYL PARATHION

298-00-0

MEVINPHOS

7786-34-7

MIREX

2385-85-5

NITROFEN

1836-75-5

OCTAMETHYLDIPHOSPHORAMIDE

152-16-9

PARATHION

56-38-2

PENTACHLOROPHENOL

87-86-5

PHENYLMERCURIC OLEATE [PMO]

EDF-185

PHOSPHAMIDON

13171-21-6

PYRIMINIL

53558-25-1

SAFROLE

94-59-7

SODIUM ARSENATE

13464-38-5

SODIUM ARSENITE

7784-46-5

2,4,5-T

93-76-5

TERPENE POLYCHLORINATES (STROBANE6)

8001-50-1

THALLIUM(I) SULFATE

7446-18-6

2,4,5-TP ACID (SILVEX)

93-72-1

TRIBUTYLTIN COMPOUNDS

EDF-184

2,4,5-TRICHLOROPHENOL

95-95-4

VINYL CHLORIDE

75-01-4

G. DMSO. The use of Dimethylsulfoxide (DMSO) in the production of Medical Marijuana shall be prohibited and possession of DMSO upon the Licensed Premises is prohibited.

H. Adulterants. An Optional Premises Cultivation Operation may not treat or otherwise adulterate Medical Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell.

I. Independent Health and Sanitary Audit

1. State Licensing Authority May Require A Health and Sanitary Audit

a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require an Optional Premises Cultivation Operation to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Optional Premises Cultivation Operation is in compliance with the requirements set forth in this Rule and other applicable public health or sanitary laws and regulations.

b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with an Optional Premises Cultivation Operation. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

c. The Optional Premises Cultivation Operation will be responsible for all costs associated with the independent health and sanitary audit.

2. When Independent Health and Sanitary Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:

a. An Optional Premises Cultivation Operation does not provide requested records related to the use of Pesticide or other agricultural chemicals during in the cultivation process;

b. The Division has reasonable grounds to believe that the Optional Premises Cultivation Operation is in violation of one or more of the requirements set forth in this rule or other applicable public health or sanitary laws, rules or regulations;

c. The Division has reasonable grounds to believe that the Optional Premises Cultivation Operation was the cause or source of contamination of Medical Marijuana or Medical Marijuana Concentrate; or

d. Multiple Harvest Batches or Production Batches produced by the Optional Premises Cultivation Operation failed contaminant testing.

3. Compliance Required. An Optional Premises Cultivation Operation must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this Rule.

4. Suspension of Operations

a. If the State Licensing Authority has objective and reasonable grounds to believe and finds upon reasonable ascertainment of the underlying facts that the public health, safety or welfare imperatively requires emergency action and incorporates such findings into its order, it may order summary suspension of the Optional Premises Cultivation Operation's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

b. Prior to or following the issuance of such an order, Optional Premises Cultivation Operation may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.

i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

ii. If an agreement to suspend operations is reached, then the Optional Premises Cultivation Operation may continue to care for its inventory and conduct any necessary internal business operations but it may Transfer Medical Marijuana or Medical Marijuana Concentrate to other Medical Marijuana Business during the period of time specified in the agreement.

J. Contaminated Product. Unless otherwise permitted by these rules:

1. A Medical Marijuana Optional Premises Cultivation Operation shall not accept or Transfer to another Medical Marijuana Business or any other Person any Medical Marijuana or Medical Marijuana Concentrate that has failed required testing pursuant to Rule M 1501 or Rule M 1503.

2. If A Medical Marijuana Optional Premises Cultivation Operation possesses any Medical Marijuana or Medical Marijuana Concentrate that failed required testing pursuant to Rule M 1501 or Rule M 1503, the Optional Premises Cultivation Operation shall assure that all Medical Marijuana and Medical Marijuana Concentrate that failed required testing is destroyed safely in accordance with Rule M 307.

K. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose – M 505

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F),12-43.3-402(6), and 12-43.3-404(10), C.R.S. The purpose of this rule is to permit laboratory testing of Medical Marijuana and establish minimum health and safety regulation for Optional Premises Cultivation Operation. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses.

M 505 – Optional Premises Cultivation Operation: Testing

A. Samples on Demand. Medical Marijuana Optional Premises Cultivation Operation shall, upon request of the Division, submit a sufficient quantity of Medical Marijuana to a Retail or Medical Marijuana Testing Facility to enable laboratory or chemical analysis thereof. The Division will notify the Licensee of the results of the analysis. See Rule M. 309 – Medical Marijuana Business: Inventory Tracking System and Rule M 901 – Business Records Required.

B. Samples Provided for Testing.

1. Repealed.1.5. This Rule M 505(B)(1.5) is effective beginning July 1, 2016. A Medical Marijuana Optional Premises Cultivation Operation may provide Samples of its Medical Marijuana to a Medical Marijuana Testing Facility for testing and research purposes. The Optional Premises Cultivation Operation shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.

Basis and Purpose – M 506

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), and 12-43.3-202(2.5)(a)(1)(A) - (F), C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at an Optional Premises Cultivation Operation and standards for the production of those concentrate.

M 506 – Optional Premises Cultivation Operation: Medical Marijuana Concentrate Production

A. Permitted Production of Certain Categories of Medical Marijuana Concentrate. An Optional Premises Cultivation Operation may only produce Water-Based Medical Marijuana Concentrate on its Licensed Premises and only in an area clearly designated for concentrate production on the current diagram of the Licensed Premises. See Rule M 901- Business Records Required. No other method of production or extraction for Medical Marijuana Concentrate may be conducted within the Licensed Premises of an Optional Premises Cultivation Operation unless the Owner(s) of the Optional Premises Cultivation Operation also has a valid Medical Marijuana-Infused Products Manufacturer license and the room in which Medical Marijuana Concentrate is to be produced is physically separated from all cultivation areas and has clear signage identifying the room.

B. Safety and Sanitary Requirements for Concentrate Production. If an Optional Premises Cultivation Operation produces Water-Based Medical Marijuana Concentrate, then all areas in which those concentrate are produced and all Owners and Occupational Licensees engaged in the production of those concentrate shall be subject to all of requirements imposed upon a Medical Marijuana-Infused Products Manufacturer that produces Medical Marijuana Concentrate, including general requirements. See Rule M 604 – Medical Marijuana-Infused Products

Manufacturer: Health and Safety Regulations and Rule M 605 Medical Marijuana-Infused Products Manufacturer: Medical Marijuana Concentrate Production.

C. Possession of Other Categories of Medical Marijuana Concentrate.

1. It shall be considered a violation of this rule if an Optional Premises Cultivation Operation possesses a Medical Marijuana Concentrate other than a Water-Based Medical Marijuana Concentrate on its Licensed Premises unless the Owner(s) of the Optional Premises Cultivation Operation also has a valid Medical Marijuana-Infused Products Manufacturer license.

2. Notwithstanding subparagraph (C)(1) of this Rule M 505, an Optional Premises Cultivation Operation shall be permitted to possess Solvent-Based Medical Marijuana Concentrate only when the possession is due to the Transfer of Medical Marijuana flower or trim that failed microbial testing to a Medical Marijuana-Infused Products Manufacturing Facility for processing into a Solvent-Based Medical Marijuana Concentrate, and the Medical Marijuana-Infused Products Manufacturing Facility Transfers the resultant Solvent-Based Medical Marijuana Concentrate back to the originating Optional Premises Cultivation Operation.

a. The Optional Premises Cultivation Operation shall comply with all requirements in Rule M 1507(B.1) when having Solvent-Based Medical Marijuana Concentrate manufactured out of Medical Marijuana flower or trim that failed microbial testing.

b. The Optional Premises Cultivation Operation is responsible for submitting the Solvent-Based Medical Marijuana Concentrate for all required testing for contaminants pursuant to Rule M 1501 – Medical Marijuana Testing Program – Contaminant Testing, for potency pursuant to Rule M 1503 – Medical Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Medical Marijuana Rules or Medical Marijuana Code.

M 600 Series – Medical Marijuana-Infused Products Manufacturers

Basis and Purpose – M 601

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I) , 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F), 12-43.3-406(1)(c), 12-43.3-406(4)(b), and 12-43.3-404, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana-Infused Products Manufacturer to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

M 601 – Medical Marijuana-Infused Products Manufacturer: License Privileges

A. Privileges Granted. A Medical Marijuana-Infused Products Manufacturer shall only exercise those privileges granted to it by the State Licensing Authority.

B. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Products Manufacturing Facility may share a location with a commonly owned Medical Marijuana-Infused Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location.

C. Authorized Transfers. A Medical Marijuana-Infused Products Manufacturer may only Transfer: (1) its own Medical Marijuana-Infused Product and Medical Marijuana Concentrate to Medical Marijuana Centers, other Medical Marijuana-Infused Products Manufacturers, Licensed Research

Businesses, Medical Research Facilities, and Pesticide Manufactures; (2) Medical Marijuana that was not cultivated at its own Optional Premises Cultivation to another Medical Marijuana-Infused Products Manufacturer.

D. Manufacture of Medical Marijuana-Infused Product Authorized. A Medical Marijuana-Infused Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana-Infused Product, whether in concentrated form or that are comprised of Medical Marijuana and other ingredients intended for use or consumption, such as Edible Medical Marijuana-Infused Products, ointments, or tinctures.

E. Location Prohibited. A Medical Marijuana-Infused Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana-Infused Product in a location that is operating as a retail food establishment or a wholesale food registrant.

F. Samples Provided for Testing.

1. Repealed.

1.5. This Rule M 601(F)(1.5) is effective beginning July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. *See* Rule M 901 – Business Records Required.

G. Authorized Marijuana Transport. A Medical Marijuana-Infused Products Manufacturer is authorized to utilize a Medical Marijuana Transporter for transportation of its Medical Marijuana-Infused Product or Medical Marijuana Concentrate so long as the place where transportation orders are taken is a licensed Medical Marijuana Business and the transportation order is delivered to a Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana-Infused Products Manufacturer from transporting its own Medical Marijuana or Medical Marijuana Concentrate.

H. Compensation. A Medical Marijuana-Infused Products Manufacturer may compensate its employees using performance-based incentives.

Basis and Purpose – M 602

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVII.6), 12-43.3-202(2)(a)(XX), 12-43.3-404(3), and 12-43.3-406(1)(a), C.R.S. The Medical Code sets forth minimum requirements for written agreements between Medical Marijuana-Infused Products Manufacturers and Medical Marijuana Centers. Specifically, the written agreements must set forth the total amount of Medical Marijuana obtained from a Medical Marijuana Center Licensee to be used in the manufacturing process, and the total amount of Medical Marijuana-Infused Product to be manufactured from the Medical Marijuana obtained from the Medical Marijuana Center. This rule clarifies that the Division must approve such written agreements to ensure they meet those requirements.

M 602 – Medical Marijuana-Infused Products Manufacturer: General Limitations or Prohibited Acts

A. Contract Required. Any contract required pursuant to section 12-43.3-404(3), C.R.S., shall contain such minimum requirements as to form and substance as required by statute. All contracts need to be current and available for inspection on the Licensed Premises by the Division when requested. See Rule M 901 – Business Records and Reporting.

B. Packaging and Labeling Standards Required. A Medical Marijuana-Infused Products Manufacturer is prohibited from Transferring Medical Marijuana-Infused Product that are not

properly packaged and labeled. See Rule M 1000 Series – Labeling, Packaging, and Product Safety and Rule M 1000-1 Series – Labeling, Packaging, and Product Safety

C. Transfer to Consumer Prohibited. A Medical Marijuana-Infused Products Manufacturer is prohibited from Transferring Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a consumer.

D. Consumption Prohibited. A Medical Marijuana-Infused Products Manufacturer shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.

E. Adequate Care of Perishable Product. A Medical Marijuana-Infused Products Manufacturer must provide adequate refrigeration for perishable Medical Marijuana-Infused Product that will be consumed and shall utilize adequate storage facilities and transport methods.

F. Homogeneity of Edible Retail Marijuana Product. A Medical Marijuana-Infused Products Manufacturer must ensure that its manufacturing processes are designed so that the Cannabinoid content of any Edible Medical Marijuana-Infused Product is homogenous.

G. A Medical Marijuana-Infused Products Manufacturer shall not sell or give away Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.

H. Cultivated Medical Marijuana Sales Prohibited. A Medical Marijuana-Infused Products Manufacturer that also has an Optional Premises Cultivation Operation shall not Transfer any Medical Marijuana that it cultivates except for the Medical Marijuana contained in its Medical Marijuana-Infused Products or Medical Marijuana Concentrate.

Basis and Purpose – M 603

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVIII.6) and (XX), 12-43.3-406(3) and 12-43.3-404, C.R.S. The purpose of this rule is to require all Medical Marijuana-Infused Products Manufacturers to track all inventory from the point it is received, through any manufacturing processes, to the point of sale or transfer to another Medical Marijuana Business.

M 603 – Medical Marijuana-Infused Products Manufacturer: Inventory Tracking System

A. Minimum Tracking Requirement. A Medical Marijuana-Infused Products Manufacturer must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point they are Transferred from a commonly owned Optional Premises Cultivation Operation, Medical Marijuana Center, Medical Marijuana Transporter, or another Medical Marijuana-Infused Products Manufacturer through Transfer. *See* Rule M 309 – Medical Marijuana Business: Inventory Tracking System. A Medical Marijuana-Infused Products Manufacturer must have the ability to reconcile its inventory records with the Inventory Tracking System and the associated transaction history and sale receipts. *See* Rule M 901 – Business Records Required.

1. A Medical Marijuana-Infused Products Manufacturer is prohibited from accepting any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product without receiving a valid transport manifest generated from the Inventory Tracking System.

2. A Medical Marijuana-Infused Products Manufacturer must immediately input all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product

delivered to its Licensed Premises, accounting for all RFID tags, into the Inventory Tracking System at the time of delivery to the Medical Marijuana-Infused Products Manufacturer..

3. A Medical Marijuana-Infused Products Manufacturer must reconcile transactions to the Inventory Tracking System at the close of business each day.

Basis and Purpose – M 604

The statutory authority for this rule includes but is not limited to 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV),12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-202(2.5)(a)(III)(A)&(B), and 12-43.3-404, C.R.S. The purpose of this rule is to establish minimum health and safety regulations for Medical Marijuana-Infused Products Manufacturers. It requires all Owners and Occupational Licensees to attend a food handler training course prior to manufacturing any Edible Medical Marijuana Product. This rule also authorizes the State Licensing Authority to require that an independent consultant conduct an independent food safety audit of a Medical Marijuana Infused-Products Manufacturing Facility. This rule explains when an independent food safety audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana-Infused Products Manufacture's refusal to cooperate or pay for the audit. It sets forth general standards and basic sanitary requirements for Medical Marijuana-Infused Products Manufacturers. It covers the physical premises where the products are made as well as the individuals handling the products. The State Licensing Authority modeled this rule after those adopted by the Colorado Department of Public Health and Environment. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses and the safety of the public. Product safety requirements are being adopted to aid in making Medical Marijuana-Infused Products more readily identifiable to the general public outside of packaging as containing Medical Marijuana. While product safety requirements are stated in this rule, nothing in the requirements interferes with a manufacturer's ability to determine portions for its products or to provide a mechanism with the product for accurately measuring a portion.

M 604 – Medical Marijuana-Infused Products Manufacturer: Health and Safety Regulations

A. Training

1. Prior to engaging in the manufacture of any Edible Medical Marijuana-Infused Product each Owner or Occupational Licensee must:

   a. Have a currently valid ServSafe Food Handler Certificate obtained through the successful completion of an online assessment or print exam; or

   b. Take a food safety course that includes basic food handling training and is comparable to, or is a course given by, the Colorado State University extension service or a state, county, or district public health agency, and must maintain a status of good standing in accordance with the course requirements, including attending any additional classes if necessary. Any course taken pursuant to this rule must last at least two hours and cover the following subjects:

      i. Causes of foodborne illness, highly susceptible populations and worker illness;

      ii. Personal hygiene and food handling practices;

      iii. Approved sources of food;

      iv. Potentially hazardous foods and food temperatures;

v. Sanitization and chemical use; and

vi. Emergency procedures (fire, flood, sewer backup).

2. A Medical Marijuana-Infused Products Manufacturer must obtain documentation evidencing that each Owner or Occupational Licensee has successfully completed the examination or course required by this rule and is in good standing. A copy of the documentation must be kept on file at any Licensed Premises where that Owner or Occupational Licensee is engaged in the manufacturing of an Edible Medical Marijuana-Infused Product.

B. General Standards

1. A Medical Marijuana-Infused Products Manufacturer may be subject to inspection by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local jurisdiction restrictions related to Medical Marijuana. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

2. A Medical Marijuana-Infused Products Manufacturer that manufacturers Edible Medical Marijuana-Infused Product shall comply with all kitchen-related health and safety standards of the relevant local licensing authority and, to the extent applicable, with all Colorado Department of Public Health and Environment health and safety regulations applicable to retail food establishments, as set forth in 6 CCR 1010-2.

C. General Sanitary Requirements. The Licensee shall take all reasonable measures and precautions to ensure the following:

1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;

2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in Medical Marijuana Concentrate or Medical Marijuana-Infused Product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

3. That all persons working in direct contact with preparation of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:

a. Maintaining adequate personal cleanliness;

b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and

c. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

4. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product;

5. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product are exposed;

6. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;

7. That there is adequate safety-type lighting in all areas where Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product are processed or stored and where equipment or utensils are cleaned;

8. That the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

9. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;

10. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Medical Marijuana-Infused Products Manufacturer and used in accordance with labeled instructions;

11. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Medical Marijuana Concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance;

12. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs;

13. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable and waste water lines;

14. That each Medical Marijuana-Infused Products Manufacturer shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair;

15. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles;

16. That Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms; and

17. That storage and transport of finished Medical Marijuana-Infused Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any Container.

C.5. Product Safety.

Paragraph (C.5) is effective beginning October 1, 2016.

1. A Medical Marijuana-Infused Products Manufacturer that manufactures Edible Medical Marijuana-Infused Product shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Medical Marijuana-Infused Product it manufactures. These procedures and processes must be documented and made available on the Licensed Premises for inspection by the Division, the Colorado Department of Public Health & Environment, and local licensing authorities.

2. A Medical Marijuana-Infused Products Manufacturer may determine a standard portion of THC for each Edible Medical Marijuana-Infused Product it manufactures. If a Medical Marijuana-Infused Products Manufacturer determines a standard portion for an Edible Medical Marijuana-Infused Product, that information must be documented in the product's standard production procedure.

3. For each Edible Medical Marijuana-Infused Product, the total amount of active THC contained within the product must be documented in the standard production procedures.

4. Universal Symbol Marking Requirements.

    a. The following categories of Edible Medical Marijuana-Infused Products shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the Medical Marijuana-Infused Product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable.

        i. Chocolate

        ii. Soft confections

        iii. Hard confections or lozenges

        iv. Consolidated baked goods (e.g. cookie, brownie, cupcake, granola bar)

        v. Pressed pills and capsules

    b. The Universal Symbol marking shall:

i. Be marked, stamped, or otherwise imprinted on at least one side of the Edible Medical Marijuana-Infused Product;

ii. Be centered either horizontally or vertically on the Edible Medical Marijuana-Infused Product; and

iii. If centered horizontally on the Edible Medical Marijuana-Infused Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's width, but not less than ¼ inch by ¼ inch; or

iv. If centered vertically on the Edible Medical Marijuana-Infused Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's height, but not less than ¼ inch by ¼ inch.

c. If a Medical Marijuana-Infused Products Manufacturer elects to determine portions for an Edible Medical Marijuana-Infused Product, then the Universal Symbol shall be applied to each portion in accordance with the requirements of subsubparagraph (C.5)(4)(b) of this Rule M 604. Except that the size of the Universal Symbol marking shall be determined by the size of the portion instead of the overall product size, and shall not be less than ¼" by ¼".

d. The following categories of Edible Medical Marijuana-Infused Products are considered to be per se impracticable to mark with the Universal Symbol marking requirements, provided that they comply with the labeling and Container requirements of Rule M 1004.5 or the Rule M 1000-1 Series.

i. Loose bulk goods (e.g. granola, cereals, popcorn);

ii. Powders; and

iii. Liquid Edible Medical Marijuana-Infused Products.

5. Remanufactured Products Prohibited. A Medical Marijuana-Infused Products Manufacturer shall not utilize a commercially manufactured food product as its Edible Medical Marijuana-Infused Product. The following exceptions to this prohibition apply:

a. A food product that was commercially manufactured specifically for use by the Medical Marijuana-Infused Products Manufacturer Licensee to infuse with marijuana shall be allowed. The Licensee shall have a written agreement with the commercial food product manufacturer that declares the food product's exclusive use by the Medical Marijuana-Infused Products Manufacturer.

b. Commercially manufactured food products may be used as ingredients in a Medical Marijuana-Infused Products Manufacturer's Edible Medical Marijuana-Infused Product so long as: (1) they are used in a way that renders them unrecognizable as the commercial food product in the final Edible Medical Marijuana-Infused Product, and (2) the Medical Marijuana-Infused Products Manufacturer does not state or advertise to the consumer that the final Edible Medical Marijuana-Infused Product contains the commercially manufactured food product.

6. Trademarked Food Products. Nothing in this Rule alters or eliminates a Medical Marijuana-Infused Products Manufacturer's responsibility to comply with the trademarked food product provisions required by the Medical Code per 12-43.3-404(11)(a-c), C.R.S.

7. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit. This subparagraph (C.5)(7) is effective beginning October 1, 2017.

a. The production, Transfer, and donation of Edible Medical Marijuana-Infused Products in the following shapes is prohibited:

i. The distinct shape of a human, animal, or fruit; or

ii. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.

b. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Medical Marijuana Business. Nothing in this subsubparagraph (C.5)(7)(b) alters or eliminates a Licensee's obligation to comply with the requirements of Rule M 1001.5 – Labeling and Packaging Requirements: General Applicability or Rule R 1000-1 Series – Labeling, Packaging, and Product Safety.

c. Edible Medical Marijuana-Infused Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and

d. Edible Medical Marijuana-Infused Products that are manufactured in the shape of a marijuana leaf are permissible.

D. Standard Operating Procedures

1. A Medical Marijuana-Infused Products Manufacturer must have written standard operating procedures for each category of Medical Marijuana Concentrate and type of Medical Marijuana-Infused Product that it produces.

a. All standard operating procedures for the production of a Medical Marijuana Concentrate must follow the requirements in Rule M 605.

b. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Medical Marijuana-Infused Products Manufacturer.

2. If a Medical Marijuana-Infused Products Manufacturer makes a Material Change to its standard Medical Marijuana Concentrate or Medical Marijuana-Infused Product production process, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

E. Additives. A Medical Marijuana-Infused Products Manufacturer shall not include any Additive that is toxic within a Medical Marijuana-Infused Product; nor include any Additive for the purposes of making the product more addictive, appealing to children or misleading to patients.

F. DMSO. The use of Dimethylsulfoxide ("DMSO") in the production of Medical Marijuana Concentrate or Medical Marijuana-Infused Product shall be prohibited and possession of DMSO upon the Licensed Premises is prohibited.

G. Independent Health and Sanitary Audit

1. State Licensing Authority May Require An Independent Health and Sanitary Audit

a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Medical Marijuana-Infused Products Manufacturer to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Medical Marijuana-Infused Products Manufacturer is in compliance with the requirements set forth in this Rule or other applicable food handling laws, rules or regulations and in compliance with the concentrate production rules in Rule M 605 or other applicable laws, rules and regulations.

b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Medical Marijuana-Infused Products Manufacturer. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

c. The Medical Marijuana-Infused Products Manufacturer will be responsible for all direct costs associated with the independent health and sanitary audit.

2. When Independent Health and Sanitary Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:

a. A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the food handling training required for Owners and Occupational Licensees engaged in the production of Edible Medical Marijuana-Infused Products to the Division;

b. A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the production of Medical Marijuana Concentrate, including but not limited to, certification of its Licensed Premises, equipment or standard operating procedures, training of Owners or employees, or Production Batch specific records;

c. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer is in violation of one or more of the requirements set forth in this Rule or Rule M 605;

d. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product; or

e. Multiple Production Batches of Medical Marijuana Concentrate or Medical Marijuana-Infused Product produced by the Medical Marijuana-Infused Products Manufacturer failed contaminant testing.

3. Compliance Required. A Medical Marijuana-Infused Products Manufacturer must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this Rule.

4. Suspension of Operations

a. If the State Licensing Authority has objective and reasonable grounds to believe and finds upon reasonable ascertainment of the underlying facts that the public

health, safety or welfare imperatively requires emergency action and incorporates such findings into its order, it may order summary suspension of the Medical Marijuana-Infused Products Manufacturer's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

b. Prior to or following the issuance of such an order, the Medical Marijuana-Infused Products Manufacturer may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.

i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

ii. If an agreement to suspend operations is reached, then the Medical Marijuana-Infused Products Manufacturer may continue to care for its inventory and conduct any necessary internal business operations but it may not, Transfer Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to another Medical Marijuana Business during the period of time specified in the agreement. Depending on the condition of the Licensed Premises and required remedial measures, the Division may permit a Medical Marijuana-Infused Products Manufacturer to produce Medical Marijuana Concentrate or manufacture Medical Marijuana-Infused Product while operations have been suspended.

H. Contaminated Products. Unless otherwise permitted by these Rules:

1. A Medical Marijuana-Infused Products Manufacturer shall not accept or Transfer to another Medical Marijuana Business or any other Person any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product that has failed required testing pursuant to Rule M 1501 or Rule M 1503.

2. If a Medical Marijuana-Infused Products Manufacturer possesses Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Products that failed required testing pursuant to Rule M 1501 or Rule M 1503, the Medical Marijuana-Infused Products Manufacturer shall assure that all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product that failed required testing is safely destroyed in accordance with Rule M 307.

I. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose – M 605

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at a Medical Marijuana-Infused Products Manufacturer and establish standards for the production of those concentrate. Nothing in this rule authorizes the unlicensed practice of engineering under Article 25 of Title 12, C.R.S.

M 605 – Medical Marijuana-Infused Products Manufacturer: Medical Marijuana Concentrate Production.

A. Permitted Categories of Medical Marijuana Concentrate Production

1. A Medical Marijuana-Infused Products Manufacturer may produce Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, and Heat/Pressure-Based Medical Marijuana Concentrate

2. A Medical Marijuana-Infused Products Manufacturer may also produce Solvent-Based Medical Marijuana Concentrate using only the following solvents: butane, propane, CO2, ethanol, isopropanol, acetone, heptane, and pentane. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.

3. Beginning on July 1, 2014, a Medical Marijuana-Infused Products Manufacturer may submit a request to the Division to consider the approval of solvents not permitted for use under this Rule during the next formal rulemaking.

B. General Applicability. A Medical Marijuana-Infused Products Manufacturer that engages in the production of Medical Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:

1. Ensure that the space in which any Medical Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule M 901- Business Records Required.

2. Ensure that all applicable sanitary rules are followed. *See* Rule M 604.

3. Ensure that the standard operating procedure for each method used to produce a Medical Marijuana Concentrate on its Licensed Premises includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:

   a. Conduct all necessary safety checks prior to commencing production;

   b. Prepare Medical Marijuana for processing;

   c. Extract Cannabinoids and other essential components of Medical Marijuana;

   d. Purge any solvent or other unwanted components from a Medical Marijuana Concentrate,

   e. Clean all equipment, counters and surfaces thoroughly; and

   f. Dispose of any waste produced during the processing of Medical Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule M 307 – Waste Disposal.

4. Establish written and documentable quality control procedures designed to maximize safety for Owners and Occupational Licensees and minimize potential product contamination.

5. Establish written emergency procedures to be followed by Owners or Occupational Licensees in case of a fire, chemical spill or other emergency.

6. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Medical Marijuana Concentrate on its Licensed Premises. The training manual must include, but need not be limited to, the following topics:

    a. All standard operating procedures for each method of concentrate production used at that Licensed Premises;

    b. The Medical Marijuana-Infused Products Manufacturer's quality control procedures;

    c. The emergency procedures for that Licensed Premises;

    d. The appropriate use of any necessary safety or sanitary equipment;

    e. The hazards presented by all solvents used within the Licensed Premises as described in the safety data sheet for each solvent;

    f. Clear instructions on the safe use of all equipment involved in each process and in accordance with manufacturer's instructions, where applicable; and

    g. Any additional periodic cleaning required to comply with all applicable sanitary rules.

7. Provide adequate training to every Owner or Occupational Licensee prior to that individual undertaking any step in the process of producing a Medical Marijuana Concentrate.

    a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.

    b. The individual training an Owner or Occupational Licensee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner or Occupational Licensee can safely produce a Medical Marijuana Concentrate. *See* Rule M 901- Business Records Required.

    c. The Owner or Occupational Licensee that received the training must sign and date a document attesting that he or she can safely implement all standard operating procedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Licensed Premises and any additional period cleaning required to maintain compliance with all applicable sanitary rules. *See* Rule M 901- Business Records Required.

8. Maintain clear and comprehensive records of the name, signature and Owner or Occupational License number of every individual who engaged in any step related to the creation of a Production Batch of Medical Marijuana Concentrate and the step that individual performed. *See* Rule M 901- Business Records Required.

C. Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, and Heat/Pressure-Based Medical Marijuana Concentrate. Medical Marijuana-Infused Products Manufacturer that engages in the production of a Water-Based Medical Marijuana Concentrate or

a Food-Based Medical Marijuana Concentrate or Heat/Pressure-Based Retail Marijuana Concentrate must:

1. Ensure that all equipment, counters and surfaces used in the production of a Water-Based Medical Marijuana Concentrate, a Food-Based Medical Marijuana Concentrate, or a Heath/Pressure Based Medical Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.

2. Ensure that all equipment, counters, and surfaces used in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.

3. Ensure that any room in which dry ice is stored or used in processing Medical Marijuana into a Medical Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO_2.

4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, or a Heat/Pressure-Based Medical Marijuana Concentrate.

5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Water-Based Medical Marijuana Concentrate.

6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Medical Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade.

7. Follow all of the rules related to the production of a Solvent-Based Medical Marijuana Concentrate if a pressurized system is used in the production of a Water-Based Medical Marijuana Concentrate, a Food-Based Medical Marijuana Concentrate, or a Heat/Pressure-Based Medical Marijuana Concentrate.

D. Solvent-Based Medical Marijuana Concentrate. A Medical Marijuana-Infused Products Manufacturer that engages in the production of Solvent-Based Medical Marijuana Concentrate must:

1. Obtain a report from an Industrial Hygienist or a Professional Engineer that certifies that the equipment, Licensed Premises and standard operating procedures comply with these rules and all applicable local and state building codes, fire codes, electrical codes and other laws. If a local jurisdiction has not adopted a local building code or fire code or if local regulations do not address a specific issue, then the Industrial Hygienist or Professional Engineer shall certify compliance with the International Building Code of 2012 (http://www.iccsafe.org), the International Fire Code of 2012 (http://www.iccsafe.org) or the National Electric Code of 2014 (http://www.nfpa.org), as appropriate. Note that this Rule does not include any later amendments or editions to each Code. The Division has maintained a copy of each code, which are available to the public;

    a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Medical Marijuana into a Medical Marijuana Concentrate, then the Industrial Hygienist or Professional Engineer must:

i. Establish a maximum amount of Flammable Solvents and other flammable materials that may be stored within that Licensed Premises in accordance with applicable laws, rules and regulations.

ii. Determine what type of electrical equipment, which may include but need not be limited to outlets, lights, junction boxes, must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored in accordance with applicable laws, rules and regulations.

iii. Determine whether a gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

iv. Determine whether fire suppression system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

b. CO_2 Solvent Determination. If CO_2 is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO_2 gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or CO_2 is stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

c. Exhaust System Determination. The Industrial Hygienist or Professional Engineer must determine whether a fume vent hood or exhaust system must be installed within the room in which Medical Marijuana Concentrate are to be produced, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

d. Material Change. If a Medical Marijuana-Infused Products Manufacturer makes a Material Change to its Licensed Premises, equipment or a concentrate production procedure, in addition to all other requirements, it must obtain a report from an Industrial Hygienist or Professional Engineer re-certifying its standard operating procedures and, if changed, its Licensed Premises and equipment as well.

e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Medical Marijuana-Infused Products Manufacturer by the designer or manufacturer of any equipment used in the processing of Medical Marijuana into a Medical Marijuana Concentrate.

f. Records Retention. A Medical Marijuana-Infused Products Manufacturer must maintain copy of all reports received from an Industrial Hygienist and Professional Engineer on its Licensed Premises. Notwithstanding any other law, rule or regulation, compliance with this rule is not satisfied by storing these reports outside of the Licensed Premises. Instead the reports must be maintained on the Licensed Premises until the Licensee ceases production of Medical Marijuana Concentrate on the Licensed Premises.

2. Ensure that all equipment, counters and surfaces used in the production of a Solvent-Based Medical Marijuana Concentrate must be food-grade and must not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds and fungi and can be easily cleaned;

3. Ensure that the room in which Solvent-Based Medical Marijuana Concentrate shall be produced must contain an emergency eye-wash station;

4. Ensure that a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Medical Marijuana Concentrate;

    a. UL or ETL Listing

        i. If the system is UL or ETL listed, then a Medical Marijuana-Infused Products Manufacturer may use the system in accordance with the manufacturer's instructions.

        ii. If the system is UL or ETL listed but the Medical Marijuana-Infused Products Manufacturer intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the system, the Medical Marijuana-Infused Products Manufacturer must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.

        iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.

    b. Ethanol or Isopropanol. A Medical Marijuana-Infused Products Manufacturer Facility need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Medical Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.

5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;

    a. A Medical Marijuana-Infused Products Manufacturer must obtain a safety data sheet for each solvent used or stored on the Licensed Premises. A Medical Marijuana-Infused Products Manufacturer must maintain a current copy of the safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule M 901- Business Records Required.

    b. A Medical Marijuana-Infused Products Manufacturer is prohibited from using denatured alcohol to produce a Medical Marijuana Concentrate.

6. Ensure that all Flammable Solvents or other flammable materials, chemicals and waste are stored in accordance with all applicable laws, rules and regulations. At no time may a

Medical Marijuana-Infused Products Manufacturer store more Flammable Solvent on its Licensed Premises than the maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;

7. Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Solvent-Based Medical Marijuana Concentrate; and

8. Ensure that a trained Owner or Occupational Licensee is present at all times during the production of a Solvent-Based Medical Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.

E. Ethanol and Isopropanol. If a Medical Marijuana-Infused Products Manufacturer only produces Solvent-Based Medical Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from the requirements in paragraph D of this Rule and instead must follow the requirements in paragraph C of this Rule. Regardless of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used. The Medical Marijuana-Infused Products Manufacturer shall comply with contaminant testing required in Rule M 1501(C)(3).

F. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

M 700 Series –Medical Marijuana Testing Facilities

Basis and Purpose – M 701.5

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A), 12-43.3-310(8)(a), 12-43.3-402(6), 12-43.3-404(10), 12-43.3-405, and 12-43.3-406, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana Testing Facility Licensee to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

M 701.5 - Medical Marijuana Testing Facilities: License Privileges

A. Privileges Granted. A Medical Marijuana Testing Facility shall only exercise those privileges granted to it by the State Licensing Authority.

B. Licensed Premises. A separate License is required for each specific Medical Marijuana Testing Facility and only those privileges granted by the Medical Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises.

C. Testing of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Infused-Product Authorized. A Medical Marijuana Testing Facility may accept Samples of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Infused-Product from Medical Marijuana Businesses for testing and research purposes only, which purposes may include the provision of testing services for Samples submitted by a Medical Marijuana Business for the purpose of product development. The Division may require a Medical Marijuana Business to submit a Sample of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Infused-Product to a Medical Marijuana Testing Facility upon demand.

C.5 Testing Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product for Patients in Research Project. A Medical Marijuana Testing Facility is authorized to

accept Samples of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product from an individual person for testing under only the following conditions:

1. The individual person is:

   a. A currently registered patient pursuant to section 25-1.5-106, C.R.S.; and

   b. A participant in an approved clinical or observational study conducted by a Licensed Research Business.

2. The Medical Marijuana Testing Facility shall require the patient to produce a valid patient registry card and a current and valid photo identification. See Rule M 405(B) – Acceptable Forms of Identification.

3. The Medical Marijuana Testing Facility shall require the patient to produce verification on a form approved by the Division from the Licensed Research Business that the patient is a participant in an approved clinical or observational Research Project conducted by the Licensed Research Business and that the testing will be in furtherance of the approved Research Project.

4. A primary caregiver may transport Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product on behalf of a patient to the Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility shall require the following documentation before accepting Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product from a primary caregiver:

   a. A copy of the patient registry card and valid photo identification for the patient;

   b. A copy of the caregiver's registration with the State Department of Health pursuant to section 25-1.5-106, C.R.S. and a current and valid photo identification, see Rule M 405(B) – Acceptable Forms of Identification; and

   c. A copy of the Licensed Research Business's verification on a form approved by the Division that the patient is participating in an approved clinical or observational Research Project being conducted by the Licensed Research Business and that the testing will be in furtherance of the approved Research Project.

5. The Medical Marijuana Testing Facility shall report all results of testing performed pursuant to this Paragraph (C.5) to the Licensed Research Business identified in the verification form submitted pursuant to Paragraph (C.5)(3) or (4)(c), or as otherwise directed by the approved Research Project being conducted by the Licensed Research Business. Testing result reporting shall conform with the requirements under these Rules.

D. Product Development Authorized. A Medical Marijuana Testing Facility may develop Medical Marijuana Infused-Product, but is not authorized to engage in the manufacturing privileges described in section 12-43.3-404, C.R.S. and Rule M 601 – Medical Marijuana Infused-Products Manufacturer: License Privileges.

E. Transferring Samples to Another Licensed and Certified Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility may Transfer Samples to another Medical Marijuana Testing Facility for testing. All laboratory reports provided to or by a Medical Marijuana Business, or to a patient or primary caregiver must identify the Medical Marijuana Testing Facility that actually conducted the test.

F. Authorized Medical Marijuana Transport. A Medical Marijuana Testing Facility is authorized to utilize a licensed Medical Marijuana Transporter to transport Samples of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product for testing, in accordance with the Medical Marijuana Code and the rules adopted pursuant thereto, between the originating Medical Marijuana Business requesting testing services and the destination Medical Marijuana Testing Facility performing testing services. Nothing in this Rule requires a Medical Marijuana Business to utilize a Medical Marijuana Transporter to transport Samples of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product for testing.

Basis and Purpose – M 702

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), 12-43.3-405, 12-43.3-901 , and 35-61-105.5, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Medical Marijuana Testing Facility.

M 702 – Medical Marijuana Testing Facilities: General Limitations or Prohibited Acts

A. Prohibited Financial Interest. A Person who is a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner of an Optional Premises Cultivation, Medical Marijuana Infused-Products Manufacturing Facility, Medical Marijuana Center, Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturing Facility, or a Retail Marijuana Store shall not be a Direct Beneficial Interest Owner or an Indirect Beneficial Interest Owner of a Medical Marijuana Testing Facility.

A.2 Conflicts of Interest. The Medical Marijuana Testing Facility shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Medical Marijuana Testing Facility's testing processes or results, or that may diminish public confidence in the competency, impartiality and integrity of the Medical Marijuana Testing Facility's testing processes or results. At a minimum, employees, owners or agents of a Medical Marijuana Testing Facility who participate in any aspect of the analysis and results of a Sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Medical Marijuana Business that provided the Sample.

B. Transfer of Medical Marijuana Prohibited. A Medical Marijuana Testing Facility shall not Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Business, a consumer, or a patient or primary caregiver, except that a Medical Marijuana Testing Facility may Transfer a Sample to another Medical Marijuana Testing Facility.

C. Destruction of Received Samples. A Medical Marijuana Testing Facility shall properly dispose of all Samples it receives, that are not Transferred to another Medical Marijuana Testing Facility, after all necessary tests have been conducted and any required period of storage. *See* Rule M 307 – Waste Disposal.

D. Consumption Prohibited. A Medical Marijuana Testing Facility shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.

E. Sample Rejection. A Medical Marijuana Testing Facility shall reject any Sample where the condition of the Sample at receipt indicates that that the Sample may have been tampered with.

F. Medical Marijuana Business Requirements Applicable. A Medical Marijuana Testing Facility shall be considered a Licensed Premises. A Medical Marijuana Testing Facility shall be subject to all requirements applicable to Medical Marijuana Businesses.

G. Medical Marijuana Testing Facility – Inventory Tracking System Required. A Medical Marijuana Testing Facility must use the Inventory Tracking System to ensure all Test Batches or Samples containing Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Products are identified and tracked from the point they are Transferred from a Medical Marijuana Business, a patient, or a patient's primary caregiver through the point of Transfer, destruction, or disposal. The Inventory Tracking System reporting shall include the results of any tests that are conducted on Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product. *See* Rule M 309 – Medical Marijuana Business: Inventory Tracking System, Rule M 711 – Reporting and Inventory Tracking System, and Rule M 701.5(C.5)(5).. The Medical Marijuana Testing Facility must have the ability to reconcile its Sample records with the Inventory Tracking System and the associated transaction history. *See* Rule M 901 – Business Records Required and Rule M 711 Reporting and Inventory Tracking

H. Industrial Hemp Testing Prohibited. A Medical Marijuana Testing Facility shall not perform testing on Industrial Hemp.

I. Transporter Restrictions. A Medical Marijuana Testing Facility shall not sell or give away Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy, or receive complimentary Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from a Medical Marijuana Transporter.

Basis and Purpose – M 703

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(X), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX),12-43.3-202(2.5)(a)(I) and 12-43.3-405, C.R.S. The purpose of this rule is to establish a frame work for certification for Medical Marijuana Testing Facilities.

M 703 – Medical Marijuana Testing Facilities: Certification Requirements

A. Certification Types. If certification in a testing category is required by the Division, then the Medical Marijuana Testing Facility must be certified in the category in order to perform that type of testing.

1. Microbials;

1.5 Mycotoxins;

2. Residual solvents;

3. Pesticides; and

4. Repealed.

5. THC and other Cannabinoid potency.

B. Certification Procedures. The Medical Marijuana Testing Facility certification program is contingent upon successful on-site inspection, successful participation in Proficiency Testing, and ongoing compliance with the applicable requirements in this Rule.

1. Certification Inspection. A Medical Marijuana Testing Facility must be inspected prior to initial certification and annually thereafter by an inspector approved by the Division.

2. Standards for Certification. A Medical Marijuana Testing Facility must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: personnel qualifications, standard operating procedure manual, analytical processes, Proficiency Testing, quality control, quality assurance, security, chain of custody, Sample retention, space, records, and results reporting.

3. Personnel Qualifications

    a. Laboratory Director. A Medical Marijuana Testing Facility must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. See Rule M 704 – Medical Marijuana Testing Facilities: Personnel.

    b. Employee Competency. A Medical Marijuana Testing Facility must have a written and documented system to evaluate and document the competency in performing authorized tests for employees. Prior to independently analyzing Samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).

4. Standard Operating Procedure Manual. A Medical Marijuana Testing Facility must have a written standard operating procedure manual meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the analytes it reports and made available for testing analysts to follow at all times.

    a. The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign and date the revised version prior to use.

    b. A Medical Marijuana Testing Facility must maintain a copy of all standard operating procedures to include any revised copies for a minimum of three years. See Rule M 710 – Medical Marijuana Testing Facilities: Records Retention and Rule M 901 – Business Records Required.

5. Analytical Processes. A Medical Marijuana Testing Facility must maintain a listing of all analytical methods used and all analytes tested and reported. The Medical Marijuana Testing Facility must provide this listing to the Division upon request.

6. Proficiency Testing. A Medical Marijuana Testing Facility must successfully participate in a Division approved Proficiency Testing program in order to obtain and maintain certification.

7. Quality Assurance and Quality Control. A Medical Marijuana Testing Facility must establish and follow a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported.

8. Security. A Medical Marijuana Testing Facility must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.

9. Chain of Custody. A Medical Marijuana Testing Facility must establish a system to document the complete chain of custody for Samples from receipt through disposal.

10. Space. A Medical Marijuana Testing Facility must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state and local requirements.

11. Records. A Medical Marijuana Testing Facility must establish a system to retain and maintain all required records. *See* Rule M 710 – Medical Marijuana Testing Facilities: Records Retention and Rule M 901 – Business Records Required.

12. Results Reporting. A Medical Marijuana Testing Facility must establish processes to ensure results are reported in a timely and accurate manner. See Rule M 711 – Reporting and Inventory Tracking System.

13. Conduct While Seeking Certification. A Medical Marijuana Testing Facility, and its agents and employees, shall provide all documents and information required or requested by the Colorado Department of Public Health and Environment and its employees, and the Division and its employees in a full, faithful, truthful, and fair manner.

C. A violation of this Rule may be considered a license violation affecting public safety.

Basis and Purpose – M 704

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX),12-43.3-202(2.5)(a)(I) and 12-43.3-405, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Medical Marijuana Testing Facility.

M 704 – Medical Marijuana Testing Facilities: Personnel

A. Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Medical Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this Rule.

1. The laboratory director may also serve as a supervisory analyst or testing analyst, or both, for a Medical Marijuana Testing Facility.

2. The laboratory director for a Medical Marijuana Testing Facility must meet one of the following qualification requirements:

a. The laboratory director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or

b. The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or

c. The laboratory director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a

regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.

B. What the Laboratory Director May Delegate. The laboratory director may delegate the responsibilities assigned under this Rule to a qualified supervisory analyst, provided that such delegation is made in writing and a record of the delegation is maintained. See Rule M 901 – Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.

C. Responsibilities of the Laboratory Director. The laboratory director must:

1. Ensure that the Medical Marijuana Testing Facility has adequate space, equipment, materials, and controls available to perform the tests reported;

2. Establish and adhere to a written standard operating procedure used to perform the tests reported;

3. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

4. Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

5. Ensure that the test methodologies selected have the capability of providing the quality of results required for the level of testing the laboratory is certified to perform;

6. Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

7. Ensure that testing analysts perform the test methods as required for accurate and reliable results;

8. Ensure that the laboratory is enrolled in and successfully participates in a Division approved Proficiency Testing program;

9. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

10. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

11. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;

12. Ensure that reports of test results include pertinent information required for interpretation;

13. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;

14. Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;

15. Ensure that prior to testing any samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;

16. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process Samples, perform test procedures and report test results promptly and proficiently, avoid actual and apparent conflicts of interest, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

17. Ensure that an approved standard operating procedure manual is available to all personnel responsible for any aspect of the testing process; and

18. Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for Sample processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.

C.5 Change in Laboratory Director. In the event that the laboratory director leaves employment at the Medical Marijuana Testing Facility, the Medical Marijuana Testing Facility shall:

1. Provide written notice to the Colorado Department of Public Health and Environment and the Marijuana Enforcement Division within seven days of the laboratory director's departure; and

2. Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.

3. The Medical Marijuana Testing Facility must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.

4. Notwithstanding the requirement of subparagraph (C.5)(3), the Medical Marijuana Testing Facility may submit a waiver request to the Division Director to receive an additional 60 days to hire a permanent laboratory director provided that the Medical Marijuana Testing Facility submits a detailed oversight plan along with the waiver request.

D. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the three years of full-time laboratory experience.

E. Laboratory Testing Analyst

1. Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or have at least a

bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory testing.

2. Responsibilities. In order to independently perform any test for a Medical Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

M 705 – Basis and Purpose

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(2.5)(a)(I) and 12-43.3-405, C.R.S. The purpose of this rule is to establish standard operating procedures manual standards for the operation of a Medical Marijuana Testing Facility.

M 705 – Medical Marijuana Testing Facilities: Standard Operating Procedure Manual

A. A standard operating procedure manual must include, but need not be limited to, procedures for:

1. Sample receiving;

2. Sample accessioning;

3. Sample storage;

4. Identifying and rejecting unacceptable Samples;

5. Recording and reporting discrepancies;

6. Security of Samples, aliquots and extracts and records;

7. Validating a new or revised method prior to testing Samples to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), LOD, LOQ, and verification of the reportable range;

8. Aliquoting Samples to avoid contamination and carry-over;

9. Sample retention to assure stability for 90 days;

10. Disposal of Samples;

11. The theory and principles behind each assay;

12. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to National Institute of Standards of Technology ("NIST");

13. Special requirements and safety precautions involved in performing assays;

14. Frequency and number of control and calibration materials;

15. Recording and reporting assay results;

16. Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;

17. Pertinent literature references for each method;

18. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;

19. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns;

20. A documented system for reviewing the results of testing calibrators, controls, standards, and subject tests results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results. Are corrective actions implemented and documented, and does the laboratory contact the requesting entity; and

21. Policies and procedures to follow when Samples are requested for referral and testing by another certified Medical Marijuana Testing Facility or an approved local state agency's laboratory.

M 706 – Basis and Purpose

The statutory authority for this rule includes but is not limited to 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish analytical processes standards for the operation of a Medical Marijuana Testing Facility.

M 706 – Medical Marijuana Testing Facilities: Analytical Processes

A. Gas Chromatography ("GC"). A Medical Marijuana Testing Facility using GC must:

1. Document the conditions of the gas chromatograph, including the detector response;

2. Perform and document preventive maintenance as required by the manufacturer;

3. Ensure that records are maintained and readily available to the staff operating the equipment;

4. Document the performance of new columns before use;

5. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;

6. Establish criteria of acceptability for variances between different aliquots and different columns; and

7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

B. Gas Chromatography Mass Spectrometry ("GC/MS"). A Medical Marijuana Testing Facility using GC/MS must:

1. Perform and document preventive maintenance as required by the manufacturer;

2. Document the changes of septa as specified in the standard operating procedure;

3. Document liners being cleaned or replaced as specified in the standard operating procedure;

4. Ensure that records are maintained and readily available to the staff operating the equipment;

5. Maintain records of mass spectrometric tuning;

6. Establish written criteria for an acceptable mass-spectrometric tune;

7. Document corrective actions if a mass-spectrometric tune is unacceptable;

8. Monitor analytic analyses to check for contamination and carry-over;

9. Use selected ion monitoring within each run to assure that the laboratory compare ion ratios and retention times between calibrators, controls and Samples for identification of an analyte;

10. Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

11. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;

12. Define the criteria for designating qualitative results as positive;

13. When a library is used to qualitatively match an analyte, the relative retention time and mass spectra from a known standard or control must be run on the same system before reporting the results; and

14. Evaluate the performance of the instrument after routine and preventive maintenance (*e.g.* clipping or replacing the column or cleaning the source) prior to analyzing subject Samples.

C. Immunoassays. A Medical Marijuana Testing Facility using Immunoassays must:

1. Perform and document preventive maintenance as required by the manufacturer;

2. Ensure that records are maintained and readily available to the staff operating the equipment;

3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer; and

4. Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.

D. Thin Layer Chromatography ("TLC"). A Medical Marijuana Testing Facility using TLC must:

1. Apply unextracted standards to each thin layer chromatographic plate;

2. Include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime;

3. Include in their written procedure the storage of unused thin layer chromatographic plates;

4. Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;

5. Verify that the spotting technique used precludes the possibility of contamination and carry-over;

6. Measure all appropriate RF values for qualitative identification purposes;

7. Use and record sequential color reactions, when applicable;

8. Maintain records of thin layer chromatographic plates; and

9. Analyze an appropriate matrix blank with each batch of Samples analyzed.

E. High Performance Liquid Chromatography ("HPLC"). A Medical Marijuana Testing Facility using HPLC must:

1. Perform and document preventive maintenance as required by the manufacturer;

2. Ensure that records are maintained and readily available to the staff operating the equipment;

3. Monitor and document the performance of the HPLC instrument each day of testing;

4. Evaluate the performance of new columns before use;

5. Create written standards for acceptability when eluting solvents are recycled;

6. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; and

7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

F. Liquid Chromatography Mass Spectroscopy ("LC/MS"). A Medical Marijuana Testing Facility using LC/MS must:

1. Perform and document preventive maintenance as required by the manufacturer;

2. Ensure that records are maintained and readily available to the staff operating the equipment;

3. Maintain records of mass spectrometric tuning;

4. Document corrective actions if a mass-spectrometric tune is unacceptable;

5. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

6. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;

7. Compare two transitions and retention times between calibrators, controls and Samples within each run;

8. Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; and

9. Evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results.

G. Other Analytical Methodology. A Medical Marijuana Testing Facility using other methodology or new methodology must:

1. Implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices prior to reporting results. Validation of other or new methodology must include when applicable, but is not limited to:

a. Verification of Accuracy

b. Verification of Precision

c. Verification of Analytical Sensitivity

d. Verification of Analytical Specificity

e. Verification of the LOD

f. Verification of the LOQ

g. Verification of the Reportable Range

h. Identification of Interfering Substances

2. Validation of the other or new methodology must be documented.

3. Prior to use, other or new methodology must have a standard operating procedure approved and signed by the laboratory director.

4. Testing analysts must have documentation of competency assessment prior to testing Samples.

5. Any changes to the approved other or new methodology must be revalidated and documented prior to testing Samples.

M 707 – Basis and Purpose

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(2)(a)(I) and 12-43.3-405, C.R.S. The purpose of this rule is to establish a proficiency testing program for Medical Marijuana Testing Facilities.

M 707 – Medical Marijuana Testing Facilities: Proficiency Testing

This Rule shall be effective on July 1, 2016.

A. Proficiency Testing Required. A Medical Marijuana Testing Facility must participate in a Proficiency Testing Program for each approved category in which it seeks certification under Rule M 703 – Medical Marijuana Testing Facilities: Certification Requirements.

B. Participation in Designated Proficiency Testing Event. If required by the Division as part of certification, the Medical Marijuana Testing Facility must have successfully participated in a proficiency test in the category for which it seeks certification, within the preceding 12 months.

C. Continued Certification. To maintain continued certification, a Medical Marijuana Testing Facility must participate in the designated proficiency testing program with continued satisfactory performance as determined by the Division as part of certification. The Division may designate a local agency, state agency, or independent third-party to provide Proficiency Testing.

D. Analyzing Proficiency Testing Samples. A Medical Marijuana Testing Facility must analyze Proficiency Testing Samples using the same procedures with the same number of replicate analyses, standards, testing analysts and equipment as used in its standard operating procedures.

E. Proficiency Testing Attestation. The laboratory director and all testing analysts that participated in a Proficiency Testing must sign corresponding attestation statements.

F. Laboratory Director Must Review Results. The laboratory director must review and evaluate all Proficiency Testing results.

G. Remedial Action. A Medical Marijuana Testing Facility must take and document remedial action when a score of less than 100% is achieved on any test during a Proficiency Test. Remedial action documentation must include a review of Samples tested and results reported since the last successful proficiency testing event. A requirement to take remedial action does not necessarily indicate unsatisfactory participation in a Proficiency Testing event.

H. Unsatisfactory Participation in Proficiency Testing Event. Unless the Medical Marijuana Testing Facility positively identifies at least 80% of the target analytes tested, participation in the Proficiency Testing will be considered unsatisfactory. A positive identification must include accurate quantitative and qualitative results as applicable. Any false positive results reported will be considered an unsatisfactory score for the proficiency testing event.

I. Consequence of Unsatisfactory Participation in Proficiency Testing Event. Unsuccessful participation in a Proficiency Testing event may result in limitation, suspension or revocation of Rule M 703 certification.

M 708 – Basis and Purpose

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(2.5)(a)(I) and 12-43.3-405, C.R.S. The purpose of this rule is to establish quality assurance and quality assurance standards for a Medical Marijuana Testing Facility.

M 708 – Medical Marijuana Testing Facilities: Quality Assurance and Quality Control

This Rule shall be effective on July 1, 2016.

A. Quality Assurance Program Required. A Medical Marijuana Testing Facility must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur and must include, but is not limited to:

1. Review of instrument preventive maintenance, repair, troubleshooting and corrective actions documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;

2. Review by the laboratory director or designated supervisory analyst of all ongoing quality assurance; and

3. Review of the performance of validated methods used by the Medical Marijuana Testing Facility to include calibration standards, controls and the standard operating procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.

B. Quality Control Measures Required. A Medical Marijuana Testing Facility must establish, monitor and document on an ongoing basis the quality control measures taken by the laboratory to ensure the proper functioning of equipment, validity of standard operating procedures and accuracy of results reported. Such quality control measures must include, but shall not be limited to:

1. Documentation of instrument preventive maintenance, repair, troubleshooting and corrective actions taken when performance does not meet established levels of quality;

2. Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;

3. Cleaning, maintaining and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;

4. Annually verifying and documenting the accuracy of thermometers using a NIST traceable reference thermometer;

5. Recording temperatures on all equipment when in use where temperature control is specified in the standard operating procedures manual, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;

6. Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;

7. Avoiding mixing different lots of reagents in the same analytical run;

8. Performing and documenting a calibration curve with each analysis using at minimum three calibrators throughout the reporting range;

9. For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of samples analyzed;

10. For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;

11. Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;

12. For multi-analyte assays, performing and documenting calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run;

13. Analyzing an appropriate matrix blank and control with each analytical run, when available;

14. Analyzing calibrators and controls in the same manner as unknowns;

15. Documenting the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the Standard Operating Procedure is met;

16. Documenting all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the Standard Operating Procedure;

17. Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and

18. Performing testing analysts that follow the current standard operating procedures manual for the test or tests to be performed.

M 709 – Basis and Purpose

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(2.5)(a)(I) and 12-43.3-405, C.R.S. The purpose of this rule is to establish chain of custody standards for a Medical Marijuana Testing Facility. In addition, it establishes the requirement that a Medical Marijuana Testing Facility follow an adequate chain of custody for Samples it maintains.

M 709 – Medical Marijuana Testing Facilities: Chain of Custody

This Rule shall be effective on July 1, 2016.

General Requirements. A Medical Marijuana Testing Facility must establish an adequate chain of custody and Sample requirement instructions that must include, but not be limited to;

1. Issue instructions for the minimum Sample requirements and storage requirements;

2. Document the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the Sample;

3. Document the condition and amount of Sample provided at the time of receipt;

4. Document all persons handling the original Samples, aliquots, and extracts;

5. Document all Transfers of Samples, aliquots, and extracts referred to another certified Medical Marijuana Testing Facility Licensee for additional testing or whenever requested by a client;

6. Maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized;

7. Secure the Laboratory during non-working hours;

8. Secure short and long-term storage areas when not in use;

9. Utilize a secured area to log-in and aliquot Samples;

10. Ensure Samples are stored appropriately; and

11. Document the disposal of Samples, aliquots, and extracts.

Basis and Purpose – M 710

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(2.5)(a)(I) and 12-43.3-405, C.R.S. The purpose of this rule is to establish records retention standards for a Medical Marijuana Testing Facility.

M 710 – Medical Marijuana Testing Facilities: Records Retention

This Rule shall be effective on July 1, 2016.

A. General Requirement. A Medical Marijuana Testing Facility must maintain all required business records. *See* Rule M901 - Business Records Required.

B. Specific Business Records Required: Records Retention. A Medical Marijuana Testing Facility must establish processes to preserve records in accordance with Rule M 901 that includes, but is not limited to;

1. Test Results, including final and amended reports, and identification of analyst and date of analysis;

2. Quality Control and Quality Assurance Records, including accession numbers, Sample type, and acceptable reference range parameters;

3. Standard Operating Procedures;

4. Personnel Records;

5. Chain of Custody Records;

6. Proficiency Testing Records; and

7. Analytical Data to include data generated by the instrumentation, raw data calibration standards, and curves. .

C. Repealed.

Basis and Purpose – M 711

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(2.5)(a)(I) and 12-43.3-405, C.R.S. The purpose of this rule is to establish reporting standards for a Medical Marijuana Testing Facility.

M 711 – Reporting and Inventory Tracking System

Required Procedures. A Medical Marijuana Testing Facility must establish procedures to ensure that results are accurate, precise and scientifically valid prior to reporting such results.

A. Reports. Every final report, whether submitted to the Division, to a Medical Marijuana Business or to any other Person authorized to receive the report, must include the following:

1. Report quantitative results that are only above the lowest concentration of calibrator or standard used in the analytical run;

2. Verify results that are below the lowest concentration of calibrator or standard and above the LOQ by using a blank and a standard that falls below the expected value of the analyte in the sample in duplicate prior to reporting a quantitative result;

3. Qualitatively report results below the lowest concentration of calibrator or standard and above the LOD as either trace or using a non-specific numerical designation;

4. Adequately document the available external chain of custody information;

5. Ensure all final reports contain the name and location of the Medical Marijuana Testing Facility that performed the test, name and unique identifier of sample, submitting client, Sample received date, date of report, type of Sample tested, test result, units of measure, and any other information or qualifiers needed for interpretation when applicable to the test method and results being reported, to include any identified and documented discrepancies; and

6. Provide the final report to the Division, as well as the Medical Marijuana Business and/or any other Person authorized to receive the report in a timely manner; and

7. Repealed.

B. Inventory Tracking System. Each Medical Marijuana Testing Facility shall:

1. Report all test results to the Division as part of daily reconciliation by the close of business and in accordance with all Inventory Tracking System Procedures under Rule M 309 – Medical Marijuana Businesses: Inventory Tracking System. The requirement to report all test results includes:

a. Both positive and negative test results;

b. Results from both mandatory and voluntary testing; and

c. For quantitative tests, a quantitative value.

2. As part of Inventory Tracking System reporting, when results of tested Samples exceed maximum levels of allowable potency or contamination, or otherwise result in failed potency, homogeneity, or contaminant testing, the Medical Marijuana Testing Facility shall, in the Inventory Tracking System, indicate failed test results for the Inventory Tracking System package associated with the failed Sample. This requirement only applies to testing of Samples that are comprised of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

C. Violation affecting public safety. Violation of this Rule may constitute a license violation affecting public safety

Basis and Purpose – M 712

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.4-203(2.5)(a)(I), 12-43.3-202(2)(a)(XIV), 12-43.4-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XX), and 12-43.3-405, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish the portion of the Division's mandatory testing and random sampling program that is applicable to Medical Marijuana Testing Facilities. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of Senate Bill 15-260. Section 1 of the bill required the State Licensing Authority

to establish an acceptable potency variance. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Medical Code.

M 712 – Medical Marijuana Testing Facilities: Sampling and Testing Program

A. Division Authority. The Division may require that a Test Batch be submitted to a specific Medical Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.

B. Test Batches

1. Medical Marijuana and Medical Marijuana Concentrate. A Medical Marijuana Testing Facility must establish a standard minimum weight of Medical Marijuana and Medical Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.

2. Medical Marijuana Infused-Product. A Medical Marijuana Testing Facility must establish a standard number of Samples it requires to be included in each Test Batch of Medical Marijuana Infused-Product for every type of test that it conducts. *See* Rule M 1504 – Medical Marijuana Testing Program – Sampling Procedures.

C. Rejection of Test Batches

1. A Medical Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.

2. A Medical Marijuana Testing Facility may not accept a Test Batch that it knows was not taken in accordance with these rules, except a Medical Marijuana Testing Facility May Accept a Test Batch that was collected by Division representatives or that was collected by a Licensee pursuant to Division direction.

D. Notification of Medical Marijuana Business. If Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product failed a contaminant test, then the Medical Marijuana Testing Facility must immediately (1) notify the Medical Marijuana Business that submitted the Test Batch or Sample for testing and any Person as directed by an approved Research Project being conducted by a Licensed Research Business; and (2) report the failure in accordance with the Inventory Tracking System reporting requirements in Rule R 711(B).

E. Permissible Levels of Contaminants. If Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product is found to have a contaminant in levels exceeding those established as permissible under this Rule, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this rule, the Division reserves the right to determine, upon good cause and reasonable grounds, that a particular Test Batch presents a risk to the public health or safety and therefore shall be considered to have failed a contaminant test.

1. Microbials (Bacteria, Fungus)

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
–Shiga-toxin producing Escherichia coli (STEC)*- Bacteria	< 1 Colony Forming Unit (CFU)	
Salmonella species* – Bacteria	< 1 Colony Forming Unit (CFU)	
Total Yeast and Mold	< 10^4 Colony Forming Unit (CFU)	

*The Medical Marijuana Testing Facility shall contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits

2. Mycotoxins

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
Aflatoxins (B1, B2, G1, and G2)	< 20 parts per billion (PPB) (total of B1 + B2 + G1 + G2)	
Ochratoxin A	< 20 parts per billion (PPB)	

3. Residual Solvents

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
Acetone	< 1,000 Parts Per Million (PPM)	
Butanes	< 1,000 Parts Per Million (PPM)	
Ethanol***	< 1,000 Parts Per Million (PPM)	
Heptanes	< 1,000 Parts Per Million (PPM)	
Isopropyl Alcohol	< 1,000 Parts Per Million (PPM)	
Propane	< 1,000 Parts Per Million (PPM)	
Benzene**	< 2 Parts Per Million (PPM)	
Toluene**	< 180 Parts Per Million (PPM)	
Pentane	< 1,000 Parts Per Million (PPM)	
Hexane**	< 60 Parts Per Million (PPM)	
Total Xylenes (m,p, o-xylenes)**	< 430 Parts Per Million (PPM)	
Any other solvent not permitted for use pursuant to Rule M 605.	None Detected	

** Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use per Rule M 605, limits have been listed here accordingly.

***Note. If the Medical Marijuana Concentrate or Medical Marijuana-Infused Product intended use is oral consumption or skin and body products only this Solvent-Based Medical Marijuana Concentrate limit for ethanol does not apply. If the Medical Marijuana Concentrate or Medical Marijuana-Infused Product intended use includes inhaled product, this Solvent-Based Medical Marijuana Concentrate limit for ethanol applies.

4. Metals

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
Metals (Arsenic, Cadmium, Lead and Mercury)	Lead – Max Limit: < 1.0 ppm Arsenic – Max Limit: < 0.4 ppm Cadmium – Max Limit: < 0.4 ppm Mercury – Max Limit: < 0.2 ppm	Flower; Water-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate

5. Pesticides

Substance	**Detection Limits**	**Product to be Tested**
Abamectin (Avermectins: B1a & B1b)	< 0.07 Parts Per Million (PPM)	
Azoxystrobin	< 0.02 Parts Per Million (PPM)	
Bifenazate	< 0.02 Parts Per Million (PPM)	
Etoxazole	< 0.01 Parts Per Million (PPM)	
Imazalil	< 0.04 Parts Per Million (PPM)	
Imidacloprid	< 0.02 Parts Per Million (PPM)	
Malathion	< 0.05 Parts Per Million (PPM)	
Myclobutanil	< 0.04 Parts Per Million (PPM)	
Permethrin (mix of isomers)	< 0.04 Parts Per Million (PPM)	
Spinosad (Mixture of A and D)	< 0.06 Parts Per Million (PPM)	
Spiromesifen	< 0.03 Parts Per Million (PPM)	
Spirotetramat	< 0.02 Parts Per Million (PPM)	
Tebuconazole	< 0.01 Parts Per Million (PPM)	

6. Other Contaminants

Pesticide	If the Test Batch is found to contain a prohibited Pesticide not listed in Paragraph (5) above, or the improper application of a permitted Pesticide, then that Test Batch shall be considered to have failed contaminant testing.
Chemicals	If Test Batch is found to contain levels of any chemical that could be toxic if consumed or as applied, then the Division may determine that the Test Batch has failed contaminant testing.
Microbials	If Test Batch is found to contain levels of any microbial that could be toxic if consumed or present, then the Division may determine that the Test Batch has failed contaminant testing.

7. Division Notification. A Medical Marijuana Testing Facility must notify the Division by timely input in the Inventory Tracking System if a Test Batch is found to contain levels of a contaminant not listed within this rule that could be injurious to human health if consumed. *See* Rule M 711 – Reporting and Inventory Tracking System.

F. Potency Testing

1. Cannabinoids Potency Profiles. A Medical Marijuana Testing Facility may test and report results for any Cannabinoid provided the test is conducted in accordance with the Division's Medical Marijuana Testing Facility's standard operating procedures Certification Policy Statement.

2. Reporting of Results

a. For potency tests on Medical Marijuana and Medical Marijuana Concentrate, results must be reported by listing a single percentage concentration for each Cannabinoid that represents an average of all Samples within the Test Batch. This includes reporting of Total THC in addition to each Cannabinoid required in Rule M 1503.

b. For potency tests conducted on Medical Marijuana Infused-Product, results must be reported by listing the total number of milligrams contained within a single Medical Marijuana-Infused Product unit for sale for each Cannabinoid and stating whether the THC content is homogenous.

3. Testing Medical Marijuana Ready for Transfer. All potency tests must occur at the time the Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product has completed all steps required prior to Transfer to another Medical Marijuana Business as outlined in the Medical Marijuana Testing Facility's standard operating procedures.

4. Failed Potency Tests for Medical Marijuana Infused-Product

a. If the THC content of a Medical Marijuana Infused-Product is determined through testing not to be homogenous, then it shall be considered to have failed potency testing. A Medical Marijuana Infused-Product shall be considered not to be homogenous if 10% of the infused portion of the Medical Marijuana Infused-Product contains more than 20% of the total THC contained within entire Medical Marijuana Infused-Product.

b. If an individually packaged Edible Medical Marijuana-Infused Product is determined to have more than the total milligrams of THC stated on the Container, or less than the total milligrams of THC stated on the Container, then the Test Batch shall be considered to have failed potency testing. Except that the potency variance provided for in subparagraph (F)(5) of this Rule M 712 shall apply to potency testing.

5. Potency Variance. A potency variance of no more than plus or minus 15% is allowed.

M 800 Series – Transport and Storage

Basis and Purpose – M 801

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6) 12-43.3-202(2)(a)(XX) and 12-43.3-406, C.R.S. The purpose of the rule is to provide clarity as to the requirements associated with the transport and delivery of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product between Licensed Premises. It also prescribes the manner in which licensed entities will track inventory in the transport process to prevent diversionary practices.

M 801 – Transport: All Medical Marijuana Businesses

A. Persons Authorized to Transport. Except as provided in the Rule M 1600 Series, any individual who transports Medical Marijuana, Medical Marijuana Vegetative plants, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product on behalf of a Medical Marijuana Business must hold a valid Occupational License and must be an employee or Owner of the Medical Marijuana Business. An individual who does not possess a current and valid Occupational License from the State Licensing Authority may not transport Medical Marijuana, Medical Marijuana Vegetative plants, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product between Licensed Premises.

B. Transport Between Licensed Premises.

1. Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product shall only be transported by Licensees between Licensed Premises; between Licensed Premises and a permitted off-premises storage facility; between Licensed Premises and a Medical Research Facility; and between Licensed Premises and a Pesticide Manufacturer. Licensees transporting Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product are responsible for ensuring that all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product are secured at all times during transport.

2. Medical Marijuana Vegetative Plants and Medical Marijuana Immature Plants.

a. Medical Marijuana Vegetative plants may only be transported between Licensed Premises and such transport shall be permitted only due to an approved change of location pursuant to rule M 206, or due to a one-time transfer pursuant to rule M 211.

b. Medical Marijuana Immature plants shall only be transported between Licensed Premises; between licensed Premises and a Medical Research Facility; and between Licensed Premises and a Pesticide Manufacturer.

c. Licensees transporting Medical Marijuana Vegetative plants and Medical Marijuana Immature plants are responsible for ensuring that all Medical Marijuana Vegetative plants and Medical Marijuana Immature plants are secure at all times during transport. Transportation of Medical Marijuana Vegetative plants and Medical Marijuana Immature plants to a permitted off-premises storage facility shall not be allowed. Transport of Medical Marijuana plants other than Vegetative plants and Immature plants shall not be allowed.

C. Inventory Tracking System-Generated Transport Manifest Required. A Licensee may only transport Medical Marijuana, Medical Marijuana Vegetative plants, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product if he or she has a hard copy of an Inventory Tracking System-generated transport manifest that contains all the information required by this rule and shall be in the format prepared by the State Licensing Authority.

1. Medical Marijuana, Medical Marijuana Immature Plants, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. A Licensee may transport Medical Marijuana, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from an originating location to multiple destination locations so long as the transport manifest correctly reflects the specific inventory destined for specific Medical Marijuana Businesses, Medical Research Facilities, and/or Pesticide Manufacturers.

2. Medical Marijuana Vegetative Plants. A Licensee shall transport Medical Marijuana Vegetative plants only from the originating Licensed Premises to the destination Licensed Premises due to a change of location that has been approved by the Division pursuant to Rule M 206, or from a Medical Marijuana Business to a Retail Marijuana Establishment due to a one-time transfer pursuant to Rule M 211.

3. Manifest for Transfers to Medical Research Facilities and Pesticide Manufacturers. A Licensee may not transport or permit the transportation of Medical Marijuana, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Products to a Medical Research Facility or Pesticide Manufacturer unless an Inventory Tracking System-generated transport manifest has been generated.

D. Motor Vehicle Required. Transport of Medical Marijuana, Medical Marijuana Vegetative plants, Medical Marijuana Immature plants, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product shall be conducted by a motor vehicle that is properly registered in the state of Colorado pursuant to motor vehicle laws, but need not be registered in the name of the Licensee. Except that when a rental truck is required for transporting Medical Marijuana Vegetative plants or Medical Marijuana Immature plants, Colorado motor vehicle registration is not required.

E. Documents Required During Transport. Transport of Medical Marijuana, Medical Marijuana Vegetative plants, Medical Marijuana Immature plants, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product shall be accompanied by a copy of the originating Medical Marijuana Business's business license, the driver's valid Owner or Occupational License, the driver's valid motor vehicle operator's license, and all required vehicle registration and insurance information.

F. Use of Colorado Roadways. State law does not prohibit the transport of Medical Marijuana, Medical Marijuana Vegetative plants, Medical Marijuana Immature plants, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product on any public road within the state of Colorado as authorized in this rule. However, nothing herein authorizes a Licensee to violate specific local ordinances or resolutions enacted by any city, town, city and county, or county related to the transport of Medical Marijuana, Medical Marijuana Vegetative plants, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

G. Preparation of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product for Transport

1. Final Weighing and Packaging. A Medical Marijuana Business shall comply with the specific rules associated with the final weighing and packaging of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product before such items

are prepared for transport pursuant to this rule. The scale used to weigh product to be transported shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S.

2. Preparation in Limited Access Area. Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product shall be prepared for transport in a Limited Access Area, including the packaging and labeling of Containers or Shipping Containers.

3. Shipping Containers. Licensees may Transfer multiple Containers of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product in a Shipping Container. The contents of Shipping Containers shall be easily accessible and may be inspected by the State Licensing Authority, local licensing authorities, and state and local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.

G.5 Required RFID Tags.

1. Licensees shall ensure that either the multiple Containers placed within a Shipping Container each have an RFID tag, or the Shipping Container itself must have an RFID tag. If the Licensee elects to place the RFID tag on the Shipping Container, the Shipping Container shall contain only one Harvest Batch, or Production Batch of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product. If a Shipping Container consists of more than one Harvest Batch or Production Batch, then each group of multiple Containers shall be affixed with an RFID tag.

2. Medical Marijuana Vegetative Plants and Medical Marijuana Immature Plants. Each Medical Marijuana Vegetative plant that is transported pursuant to this rule must have a RFID tag affixed to it prior to transport. Each receptacle containing Medical Marijuana Immature plants transported pursuant to this rule must have an RFID tag affixed prior to transport.

H. Creation of Records and Inventory Tracking

1. Use of Inventory Tracking System -Generated Transport Manifest.

a. Medical Marijuana, Medical Marijuana Immature Plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. Licensees who transport or permit the transportation of Medical Marijuana, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the Licensed Premises destined for other Licensed Premises, Medical Research Facilities, or Pesticide Manufacturers. The transport manifest may either reflect all deliveries for multiple locations within a single trip or separate transport manifests may reflect each single delivery. In either case, no inventory shall be transported without an Inventory Tracking System-generated transport manifest.

a.1 Use of a Medical Marijuana Transporter. In addition to subparagraph (H)(1)(a), Licensees shall also follow the requirements of this subparagraph (H)(1)(a.1) when a Licensee utilizes the services of a Medical Marijuana Transporter.

i. When a Medical Marijuana Business utilizes a Medical Marijuana Transporter for transporting its Medical Marijuana, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Products, the originating Licensee shall input the requisite

information on the Inventory Tracking System-generated transport manifest for the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer who will be receiving the Medical Marijuana, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Products.

ii. A Medical Marijuana Transporter is prohibited from being listed as the final destination Licensee.

iii. A Medical Marijuana Transporter shall not alter the information of the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer after the information has been entered on the Inventory Tracking System-generated transport manifest by the originating Licensee.

iv. If the Medical Marijuana Transporter is not delivering the originating Licensee's Medical Marijuana, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana- Infused Product directly to the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer, the Medical Marijuana Transporter shall communicate to the originating Licensee which of the Medical Marijuana Transporter's Licensed Premises or off-premises storage facilities will receive and temporarily store the Medical Marijuana, Medical Marijuana Immature plants, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. The originating Licensee shall input the Medical Marijuana Transporter's location address and license number on the Inventory Tracking System-generated transport manifest.

b. Medical Marijuana Vegetative Plants.

i. Licensees who transport Medical Marijuana Vegetative plants shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the originating Licensed Premises to be transported to the destination Licensed Premises due to a change of location approved by the Division pursuant to Rule M 206, or a one-time transfer pursuant to Rule M 211.

ii. Medical Marijuana Transporters are permitted to transport Medical Marijuana Vegetative plants on behalf of other Licensees due to a change of location approved by the Division pursuant to Rule M 206, or a one-time transfer pursuant to Rule M 211. The Medical Marijuana Transporter shall transport the Medical Marijuana Vegetative plants directly from the originating Licensed Premises to the final destination Licensed Premises.

2. Copy of Transport Manifest to Recipient. A Licensee shall provide a copy of the transport manifest to each Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer receiving the inventory described in the transport manifest. In order to maintain transaction confidentiality, the originating Licensee may prepare a separate Inventory Tracking System-generated transport manifest for each recipient Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer.

3. The Inventory Tracking System-generated transport manifest shall include the following:

a. Departure date and approximate time of departure;

b. Name, location address, and license number of the originating Medical Marijuana Business;

c. Name, location address, and license number of the destination Medical Marijuana Business(es), or the destination Retail Marijuana Establishment in the event of a one-time transfer; name and location address of the destination Medical Research Facility; or name and location address of the destination Pesticide Manufacturer;

c.1 Name, location address, and license number of the Medical Marijuana Transporter if applicable pursuant to M 801(H)(1)(a.1)(iv).

d. Product name and quantities (by weight or unit) of each product to be delivered to each specific destination location(s);

e. Arrival date and estimated time of arrival;

f. Delivery vehicle make and model and license plate number; and

g. Name, Occupational License number, and signature of the Licensee accompanying the transport.

I. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Medical Marijuana Business shall be responsible for all the procedures associated with the tracking of inventory that is transported between Licensed Premises. See Rule M 901 – Business Records Required.

1. Responsibilities of Originating Licensee.

a. Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. Prior to departure, the originating Medical Marijuana Business shall adjust its records to reflect the removal of Medical Marijuana or Medical Marijuana-Infused Product. The scale used to weigh product to be transported shall be tested and approved in accordance with measurement standards established in section 35-14-127, C.R.S. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.

b. Medical Marijuana Vegetative Plants and Medical Marijuana Immature Plants. Prior to departure, the originating Optional Premises Cultivation Operation shall adjust its records to reflect the removal of Medical Marijuana Vegetative plants and Medical Marijuana Immature plants. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.

2. Responsibilities of Recipient.

a. Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. Upon receipt, the receiving Licensee shall ensure that the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product received are as described in the transport manifest, If necessary, the receiving Licensee shall immediately adjust its records to reflect the receipt of inventory. The scale used to weigh product being received shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S. Entries to the inventory records shall note the Inventory Tracking System-

generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest. Medical Marijuana Transporters shall comply with all requirements of this subparagraph (l)(2)(a) except that they are not required to weigh Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Products.

i. When a Medical Marijuana Business transfers Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Research Facility or Pesticide Manufacturer, the originating Licensee is responsible for confirming delivery of the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product in the Inventory Tracking System.

b. Medical Marijuana Vegetative Plants and Medical Marijuana Immature Plants. Upon receipt, the receiving Licensee shall ensure that the Medical Marijuana Vegetative plants received are as described in the transport manifest, accounting for all RFID tags and each associated plant, and shall immediately adjust its records to reflect the receipt of inventory. Upon Receipt, the recipient Licensee shall ensure that the Medical Marijuana Immature plants received are as described in the transport manifest, accounting for all RFID tags and each receptacle containing Medical Marijuana Immature plants, and shall immediately adjust its records to reflect the receipt of inventory.

i. When a Medical Marijuana Business transfers Medical Marijuana Immature plants to a Medical Research Facility or Pesticide Manufacturer, the originating Licensee is responsible for confirming delivery of the Medical Marijuana Immature plants in the Inventory Tracking System.

3. Discrepancies.

a. Licensees. A receiving Licensee shall separately document any differences between the quantity specified in the transport manifest and the quantities received. Such documentation shall be made in the Inventory Tracking System and in any relevant business records.

b. Medical Research Facilities and Pesticide Manufacturers. In the event of a discrepancy between the quantity specified in a transport manifest and the quantity received by a Medical Research Facility or Pesticide Manufacturer, the originating Licensee shall document the discrepancy in the Inventory Tracking System and in any relevant business records, and account for the discrepancy

J. Adequate Care of Perishable Medical Marijuana-Infused Product. A Medical Marijuana Business must provide adequate refrigeration for perishable Medical Marijuana-Infused Product during transport.

K. Failed Testing. In the event Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product has failed required testing, has been contaminated, or otherwise presents a risk of cross-contamination to other Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product, such Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product may only be transported if it is physically segregated and contained in a sealed package that prevents cross-contamination.

Basis and Purpose – M 802

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6) 12-43.3-202(2)(a)(XX), and 12-43.3-406(2), C.R.S. The purpose of this rule is to establish that Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product may not be stored outside of Licensed Premises unless the Licensee obtains an off-premises storage permit.

M 802 – Off-Premises Storage of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product: All Medical Marijuana Businesses

A. Off-premises Storage Permit Authorized. A Medical Marijuana Center, Medical Marijuana-Infused Products Manufacturer, an Optional Premises Cultivation Operation, and a Medical Marijuana Testing Facility may only store Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product in their Licensed Premises or in their one permitted off-premises storage facility. Medical Marijuana Transporters are allowed to have more than one permitted off-premises storage facility.

B. Permitting. To obtain a permit for an off-premises storage facility, a Medical Marijuana Business must apply on current Division forms and pay any applicable fees. A Medical Marijuana Transporter may only apply for and hold an off-premises storage permit in a local jurisdiction that permits the operation of Medical Marijuana Centers.

C. Extension of Licensed Premises. A permitted off-premises storage facility shall constitute an extension of the Medical Marijuana Business' Licensed Premises and be subject to all to the conditions and restrictions established in Rule M 301 – Limited Access Areas.

D. Limitation on Inventory to be Stored. A Medical Marijuana Center, Medical Marijuana-Infused Products Manufacturer, and an Optional Premises Cultivation Operation may only have upon the permitted off-premises storage facility Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that are part of the particular Medical Marijuana Business's finished goods inventory. The aforementioned Licensees may not share the premises with, nor store inventory belonging to, a Medical Marijuana Business that is not commonly-owned or a Retail Marijuana Establishment.

E. Restrictions. The permitted off-premises storage facility may be utilized for storage only. A Licensee may not Transfer, cultivate, manufacture, process, test, research, or consume any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product within the premises of the permitted off-premises storage facility.

F. Display of Off-premises Storage Permit and License. The off-premises storage facility permit and a copy of the Medical Marijuana Business' license must be displayed in a prominent place within the permitted off-premises storage facility.

G. Local Licensing Authority Approval

1. Prior to submitting an application for an off-premises storage facility permit, the Licensee must obtain approval from the relevant local licensing authority.

2. A copy of the relevant local licensing authority's approval must be submitted by the Licensee in conjunction with its application for an off-premises storage facility.

3. No Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product may be stored within a permitted storage facility until the relevant local licensing authority has been provided a copy of the off-premises storage facility permit.

4. Any off-premises storage permit issued by the Division shall be conditioned upon the Medical Marijuana Business' receipt of all required local approvals.

H. Security in Storage Facility. A permitted off-premises storage facility must meet all video and security requirements applicable to a Licensed Premises.

I. Transport to or from a Permitted Off-premises Storage Facility. A Medical Marijuana Business must comply with Rule M 801 – Transport: All Medical Marijuana Businesses, when transporting any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to and from a permitted off-premises storage facility.

J. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Medical Marijuana Business shall utilize the Inventory Tracking System to track its inventories from the point of transfer to or from a permitted off-premises storage facility. See Rules M 901 – Business Records Required and M 309- Medical Marijuana Business: Inventory Tracking System.

K. Inventory Tracking System Access and Scale. Every permitted off-premises storage facility must have an Inventory Tracking System terminal and a scale tested and approved in accordance with measurement standards established in section 35-14-127, C.R.S.

L. Adequate Care of Perishable Medical Marijuana-Infused Product. A Medical Marijuana Business must provide adequate refrigeration for perishable Medical Marijuana-Infused Product and shall utilize adequate storage facilities and transport methods.

M. Consumption Prohibited. A Medical Marijuana Business shall not permit the consumption of marijuana or marijuana products on the premises of its permitted off-premises storage facility.

M 900 Series – Business Records

Basis and Purpose – M 901

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XVII), and 12-43.3-202(2)(a)(XX), C.R.S. This rule explains what business records a Licensee must maintain. It also clarifies that such records must be made available to the Division on demand. Rule R 901(B) was added due to written commentary received from an industry representative.

M 901 – Business Records Required

A. General Requirements

1. A Medical Marijuana Business must maintain the information required in this rule in a format that is readily understood by a reasonably prudent business person.

2. Each Medical Marijuana Business shall retain all books and records necessary to fully account for the business transactions conducted under its license for the current year and three preceding calendar years.

a. On premises records: The Medical Marijuana Business' books and records for the preceding six months (or complete copies of such records) must be maintained on its Licensed Premises at all times.

b. On- or off-premises records: Books and records associated with older periods may be archived on or off of the Licensed Premises.

3. The books and records must fully account for the transactions of the business and must include, but shall not be limited to:

   a. Current Employee List – This list must provide the full name and Occupational License number of each employee and all non-employee Owners, who work at a Medical Marijuana Business.

      i. Each Licensed Premises shall enter the full name and Occupational License number of every employee that works on the premises into the Inventory Tracking System. The Licensed Premises shall update its list of employees in the Inventory Tracking System within 10 days of an employee commencing or ceasing employment on the premises.

   b. Secure Facility Information – For its Licensed Premises and any associated permitted off-premises storage facility, a Medical Marijuana Business must maintain the business contact information for vendors that maintain video surveillance systems and Security Alarm Systems.

   c. Licensed Premises – Diagram of all approved Limited Access Areas and any permitted off-premises storage facilities.

   d. Visitor Log – List of all visitors entering Limited Access Areas or Restricted Access Areas.

   e. All records normally retained for tax purposes.

   f. Advertising Records – All records related to Advertising and marketing, including but not limited to, audience composition data.

   g. Waste log – Comprehensive records regarding all waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of marijuana.

   h. Surveillance logs – Surveillance logs as required by Rule M 306.

   i. Every Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol which shall be available upon request by the State Licensing Authority or Division. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule.

   j. All records normally retained for tax purposes.

   k. Testing Records – all testing records required by Rule M 710.

B. Loss of Records and Data. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this rule. Licensees are required to exercise due diligence in preserving and maintaining all required records.

C. Violation Affecting Public Safety. Violation of this rule may constitute a license violation affecting public safety.

D. Records Related to Inventory Tracking. A Medical Marijuana Business must maintain accurate and comprehensive inventory tracking records that account for, reconcile, and evidence all inventory activity for Medical Marijuana from either seed or Immature Plant stage until the Medical

Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product is destroyed or Transferred to another Medical Marijuana Business, a patient, a Medical Research Facility, or a Pesticide Manufacturer.

E. Records Related to Transport. A Medical Marijuana Business must maintain adequate records for the transport of all activities related to Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. *See* Rule M 801 – Transport: All Medical Marijuana Businesses.

F. Provision of Requested Records to the Division. A Licensee must provide on-demand access to on-premises records following a request from the Division during normal business hours or hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Division.

M 1000 Series – Labeling, Packaging, and Product Safety

Effective Date. Compliance with this M 1000 Series is mandatory until January 1, 2018. During the period January 1, 2018, to June 30, 2018, Licensees have the option of complying with this Rule M 1000 Series or with the Rule M 1000-1 Series, but must be fully compliant with at least one of those two Labeling, Packaging, and Product Safety Series. Beginning July 1, 2018, this Rule M 1000 Series is repealed, and compliance with the M 1000-1 Series is mandatory.

Basis and Purpose – M 1001.5

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(VI), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-403(3), 12-43.3-404(5), and 12-43.3-901(4)(b), C.R.S. The State Licensing Authority finds it essential to regulate and establish labeling and secure packaging requirements for Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Infused-Product. The purpose of this rule, and the rules in this series, is to ensure that all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Infused-Product are sold and delivered to lawful consumers in packaging that is not easily opened by children. Further, the State Licensing Authority believes based on written and oral comments it received through the rulemaking process that prohibiting labels that appeal to or are intended to target individuals under the age of 21 and requiring child-resistant packaging is of a state wide concern and would assist in limiting exposure and diversion to minors. One of the State Licensing Authority's primary goals is to prevent use of Medical Marijuana by children who are not registered Medical Marijuana patients. The State Licensing Authority has a compelling state interest in the reduction and prevention of accidental marijuana consumption by children. This can be achieved through avoidance of packaging designed to appeal to children and avoidance of use of the word "candy" on packaging, labeling and product. Children generally have a strong attraction to and interest in candy. "Candy" is one of the first words children learn to speak. Children rely upon packaging to deduce a product's contents. "Candy" is not medicine. This rule is in the interest of the health of the people of Colorado and is necessary for the stringent and comprehensive administration of the Medical Code. The State Licensing Authority is adopting this rule as a narrowly-tailored way to reduce or prevent accidental ingestion of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Products by children and others.

M 1001.5 – Labeling and Packaging Requirements: General Applicability

A. Ship Product Ready for Sale. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer may package smaller quantities of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Infused-Product in a Container prior to transport, provided the Containers are placed within a larger package that has an RFID tag and all required labels affixed to it. This larger package of Containers may serve as the Shipping Container. Licensees shall ensure that either each package of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product placed within a Shipping Container has an

RFID tag and all required labels affixed to each package, or the Shipping Container itself must have an RFID tag and all required labels affixed to it for the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product contained within the Shipping Container. If the Licensee elects to place the RFID tag and all required labels on the Shipping Container, the Shipping Container shall contain only one package, Harvest Batch, or Production Batch of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. If a Shipping Container holds multiple packages, each individual package shall be affixed with an RFID tag and all required labels. See Rule M 309 – Inventory Tracking System and Rule M 801 – Transport: All Medical Marijuana Businesses.

B. Inventory Tracking Compliance.

1. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer must package all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Infused-Product in accordance with all Inventory Tracking System rules and procedures.

C. Packaging May Not Be Designed to Appeal to Children. A Medical Marijuana Business shall not place any content on a Container holding Medical Marijuana, Medical Marijuana Concentrate, or a Medical Marijuana Infused-Product in a manner that specifically targets individuals under the age of 21, including but not limited to, cartoon characters or similar images.

D. Health and Benefit Claims. Labeling text on a Container may not make any false or misleading statements regarding health or physical benefits to the consumer.

E. Font Size. Labeling text on a Container must be no smaller than 1/16 of an inch.

F. Use of English Language. Labeling text on a Container must be clearly written or printed and in the English language.

G. Unobstructed and Conspicuous. Labeling text on a Container must be unobstructed and conspicuous. A Licensee may affix multiple labels to a Container, provided that none of the information required by these rules is completely obstructed.

H. Use of the Word(s) “Candy” and/or “Candies” Prohibited.

1. Licensees shall not use the word(s) “candy” and/or “candies” on the product, packaging or labeling for Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

2. Notwithstanding the requirements of subparagraph (H)(1), a licensed Medical Marijuana Business whose Identity Statement contains the word(s) “candy” and/or “candies” shall be permitted to place its Identity Statement on Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product packaging and labeling.

Basis and Purpose – M 1002.5

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(7), 12-43.3-404(5), 12-43.3-404(10), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer label each package and Container of Medical Marijuana with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana as this is a public health and safety concern.

M 1002.5 – Packaging and Labeling of Medical Marijuana by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer

A. Packaging of Medical Marijuana by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that all Medical Marijuana is placed within a sealed package that has no more than ten pounds of Medical Marijuana within it prior to transport or transfer of any Medical Marijuana to another Medical Marijuana Business. The package shall be affixed with an RFID tag in accordance with rule M 1001.5(A).

B. Labeling of Medical Marijuana Packages by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every package holding Medical Marijuana that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.

1. Required Information. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every package holding Medical Marijuana:

    a. The license number of the Optional Premises Cultivation Operation where the Medical Marijuana was grown;

    b. The Harvest Batch Number(s) assigned to the Medical Marijuana;

    c. The net weight, using a standard of measure compatible with the Inventory Tracking System, of the Medical Marijuana prior to its placement in the package; and

    d. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana.

2. Required Potency Statement. For each package of Medical Marijuana, the potency of at least the Medical Marijuana's THC and CBD shall be included on a label that is affixed to the package. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration for each cannabinoid listed, from every test conducted on that strain of Medical Marijuana cultivated by the same Optional Premises Cultivation Operation within the last six months.

3. Required Contaminant Testing Statement.

    a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Harvest Batch for microbials, mold, mildew, and filth, then the package shall be labeled with the following statement: **"The marijuana contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation has successfully validated its process regarding contaminants pursuant to rule M 1501, then the package instead shall be labeled with the following statement: **"The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

    b. When All Required Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Harvest Batch for microbials, mold, mildew, and filth, and the required test(s) passed, then the package shall be labeled with

the following statement: **"The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

c. Nothing in this rule permits a Medical Marijuana Business to Transfer Medical Marijuana that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

C. Labeling of Medical Marijuana Containers by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. If an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer packages Medical Marijuana within a Container that is then placed within a larger package, each Container must be affixed with a label(s) containing all of the information required by Rule M 1002.5(B), except that the net weight statement required by Rule M 1002.5(B)(1)(c) shall be based upon the weight in the Container and not the larger package or Shipping Container.

Basis and Purpose – M 1003.5

The statutory authority for this includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(7), 12-43.3-404(5), 12-43.3-404(10), 12-43.3-404(11)(b-c), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer labels each package and Container of Medical Marijuana Concentrate with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana Concentrate because it is a public health and safety concern.

M 1003.5 – Packaging and Labeling of Medical Marijuana Concentrate by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer

A. Packaging of Medical Marijuana Concentrate by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that all Medical Marijuana Concentrate is placed within a sealed package that has no more than one pound of Medical Marijuana Concentrate within it prior to transport or transfer to another Medical Marijuana Business. The package shall be affixed with an RFID tag in accordance with rule M 1001.5(A).

B. Labeling Medical Marijuana Concentrate Package by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every package holding Medical Marijuana Concentrate that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.

1. Required Information. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every package holding Medical Marijuana Concentrate:

a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Concentrate was grown;

b. The license number of the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Concentrate;

c. The Production Batch Number assigned to the Medical Marijuana Concentrate contained within the package;

d. The net weight, using a standard of measure compatible with the Inventory Tracking System, of the Medical Marijuana Concentrate prior to its placement in the package;

e. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Concentrate contained within; and

f. A complete list of solvents and chemicals used to create the Medical Marijuana Concentrate.

2. Required Potency Statement. For each package of Medical Marijuana Concentrate , the potency of at least the Medical Marijuana Concentrate's THC and CBD shall be included on a label that is affixed to the package. The potency shall be expressed in milligrams for each cannabinoid.

3. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed.

i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, then the package shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package has not been tested for contaminants."** Except that when a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, the package instead shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Food- or Water-Based Medical Marijuana Concentrate for microbials, mold, and mildew, then the package shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, then the package instead shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

b. When All Required Contaminant Tests Are Performed and Passed.

i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, and the required test(s) passed, then the package shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained**

within this package complies with the mandatory contaminant testing required by rule M 1501."

ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch for microbials, mold, and mildew, and the required test(s) passed, then the package shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

c. Nothing in this rule permits a Medical Marijuana Business to Transfer Medical Marijuana Concentrate that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

C. Labeling of Medical Marijuana Concentrate Containers by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. If an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer packages a Medical Marijuana Concentrate within a Container that is then placed within a larger package, each Container must be affixed with a label(s) containing all of the information required by Rule M 1003.5(B), except that the net weight statement required by Rule M 1003.5(B)(1)(d) shall be based upon the weight in the Container and not the package or Shipping Container.

Basis and Purpose – M 1004.5

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(2)(a)(I-III), 12-43.3-402(7), 12-43.4-404(5), 12-43.4-404(10), 12-43.4-404(11), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that every Medical Marijuana-Infused Products Manufacturer labels each package and Container holding a Medical Marijuana Infused-Product with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper packaging and labeling techniques for each Medical Marijuana Infused-Product because it is a public health and safety concern. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of Senate Bill 15-260. Section 1 of the bill required the State Licensing Authority to establish an acceptable potency variance for correct labeling. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

Product safety requirements are being adopted to aid in making Medical Marijuana-Infused Products more readily identifiable to the general public as containing Medical Marijuana. While product safety requirements are stated in this rule, nothing in the requirements interferes with a manufacturer's ability to determine standard portions for its products or to provide a mechanism with the product for accurately measuring a standard portion.

M 1004.5 – Packaging and Labeling Requirements of a Medical Marijuana Infused-Product by a Medical Marijuana-Infused Products Manufacturer

A. Packaging of Medical Marijuana Infused-Product by a Medical Marijuana-Infused Products Manufacturer

1. General Standard. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Container holding a Medical Marijuana Infused-Product is placed in a package

prior to transport or transfer to another Medical Marijuana Business. The package shall be affixed with an RFID tag in accordance with rule M 1001.5(A).

2. Edible Medical Marijuana Infused-Product.

   a. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Edible Medical Marijuana Infused-Product is packaged within a Child-Resistant Container prior to transport or transfer to another Medical Marijuana Business.

   b. If the Edible Medical Marijuana-Infused Product contains multiple portions then it must be packaged in a Child-Resistant Container that is Resealable.

3. Medical Marijuana Infused-Product that is not Edible Medical Marijuana Infused-Product. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Medical Marijuana Infused-Product that is not an Edible Medical Marijuana Infused-Product is individually packaged within a Container prior to transport or transfer to another Medical Marijuana Business.

B. Labeling of Medical Marijuana Infused-Product Containers by a Medical Marijuana-Infused Products Manufacturer. A Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every Container holding a Medical Marijuana Infused-Product that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.

1. Required Information (General). Every Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every Container holding a Medical Marijuana Infused-Product:

   a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Infused-Product was grown;

   b. The Production Batch Number(s) of Medical Marijuana Concentrate(s) used in the production of the Medical Marijuana Infused-Product.

   c. The license number of the Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Infused-Product.

   d. A net weight statement.

   e. The Production Batch Number(s) assigned to the Medical Marijuana Infused-Product.

   f. A statement about whether the Container is Child-Resistant.

   h. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana-Infused Products Manufacturer that manufactured the Medical Marijuana Infused-Product. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;

   i. The Universal Symbol, which must be located on the front of the Container and no smaller than ½ of an inch by ½ of an inch, and the following statement which

must be labeled directly below the Universal Symbol: “Contains Marijuana. For Medical Use Only. Keep out of the reach of children.”

j. The following warning statements:

i. “There may be health risks associated with the consumption of this product.”

ii. “This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S.”

iii. “This product was produced without regulatory oversight for health, safety, or efficacy.”

iv. “There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant.”

k. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Infused-Product.

l. A complete list of solvents and chemicals used in the creation of any Medical Marijuana Concentrate that was used to produce the Medical Marijuana Infused-Product.

m. Required Potency Statement. This subsubparagraph (B)(1)(m) of rule M 1004.5 shall become effective October 1, 2017. Each Container holding a Medical Marijuana-Infused Product shall be labeled with the potency of at least the Medical Marijuana-Infused Product’s THC and CBD. The potency shall be expressed in milligrams for each cannabinoid. The potency shall be labeled either:

i. In a font size that is at least two font sizes larger than the surrounding label text and also not less than 10 point font, bold, and enclosed within an outlined shape such as a circle or square; or

ii. Highlighted with a bright color such as yellow.

2. Required Information (Edible Medical Marijuana Infused-Product). Every Medical Marijuana-Infused Products Manufacturer must ensure that the following information or statement is affixed to every Container holding an Edible Medical Marijuana Infused-Product:

a. Ingredient List. A list of all ingredients used to manufacture the Edible Medical Marijuana Infused-Product; which shall include a list of any potential allergens contained within.

b. Statement Regarding Refrigeration. If the Edible Medical Marijuana Infused-Product is perishable, a statement that the Edible Medical Marijuana Infused-Product must be refrigerated.

c. Statement of Production Date. The date on which the Edible Medical Marijuana Infused-Product was produced.

d. Statement of Expiration Date. A product expiration date, for perishable Edible Medical Marijuana Infused-Product, upon which the product will no longer be fit for consumption, or a use-by-date, upon which the product will no longer be optimally fresh. Once a label with a use-by or expiration date has been affixed to a Container holding an Edible Medical Marijuana Infused-Product, a Licensee shall not alter that date or affix a new label with a later use-by or expiration date.

3. Permissive Information (Edible Medical Marijuana Infused-Product). Every Medical Marijuana-Infused Products Manufacturer may affix a label(s) with the following information to every Container holding an Edible Medical Marijuana Infused-Product:

a. The Medical Marijuana Infused-Product's compatibility with dietary restrictions.

b. A nutritional fact panel.

4. Required Potency Statement.

a. Every Medical Marijuana-Infused Products Manufacturer must ensure that a label is affixed to the Container that includes at least the Medical Marijuana Infused-Product's THC and CBD content.

b. Nothing in this rule permits a Medical Marijuana Business to Transfer Medical Marijuana Infused-Product that has failed potency testing and has not subsequently passed the additional potency testing required by rule R 1507(C).

5. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Production Batch of Medical Marijuana Infused-Product for microbials, mold, and mildew, then the Container shall be **labeled** with the following statement: **"The Medical Marijuana Infused-Product contained within this package has not been tested for contaminants."** Except that when a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants for the particular Medical Marijuana Infused-Product pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: **"The Medical Marijuana Infused-Product contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

b. When All Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Production Batch of Medical Marijuana Infused-Product for microbials, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: **"The Medical Marijuana Infused-Product contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

c. Nothing in this rule permits a Medical Marijuana Business to Transfer Medical Marijuana Infused-Product that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

D. Labeling of Medical Marijuana Infused-Product Shipping Containers or Packages by Medical Marijuana-Infused Products Manufacturer. Prior to transporting or transferring any Medical Marijuana Infused-Product to another Medical Marijuana Business, a Medical Marijuana Manufacturing Products Facility must ensure that a label is affixed to a Shipping Container or

package holding Medical Marijuana Infused-Product that includes all of the information required by this rule. A Medical Marijuana-Infused Products Manufacturer must include the following information on every Shipping Container or package:

1. The number of Containers holding a Medical Marijuana Infused-Product within the Shipping Container or package; and

2. The license number of the Medical Marijuana-Infused Products Manufacturer(s) that produced the Medical Marijuana Infused-Product within the Shipping Container or package.

Basis and Purpose – M 1005

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(2)(a), 12-43.3-402(6), 12-43.3-402(7), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that the labeling on each Container of Medical Marijuana includes necessary and relevant information for patients, does not include health and physical benefit claims, is easily accessible to patients, and is clear and noticeable. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana because it is a public health and safety concern. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of Senate Bill 15-260. Section 1 of the bill required the State Licensing Authority to establish an acceptable potency variance for correct labeling. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

M 1005 – Packaging and Labeling of Medical Marijuana by a Medical Marijuana Center

A. Packaging of Medical Marijuana by a Medical Marijuana Center.

1. A Medical Marijuana Center must ensure that all Medical Marijuana is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.

2. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:

a. A Medical Marijuana Center shall not be required to package the Medical Marijuana in a Child-Resistant Container for sale to the patient; and

b. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.

c. If the Medical Marijuana is packaged in a Child-Resistant Container, a Medical Marijuana Center may defeat the Medical Marijuana's Child-Resistant packaging on behalf of the patient, so long as the Medical Marijuana remains with the packaging after the Child-Resistant properties have been defeated.

B. Labeling of Medical Marijuana by a Medical Marijuana Center. A Medical Marijuana Center must affix all of the information required by this rule to every Container in which Medical Marijuana is placed no later than at the time of sale to a patient:

1. A Medical Marijuana Center must include the following information on every Container:

a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana was grown;

b. The license number of the Medical Marijuana Center that sold the Medical Marijuana to the patient;

c. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana Center that sold the Medical Marijuana to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;

d. The Harvest Batch Number(s) assigned to the Medical Marijuana within the Container;

e. The date of sale to the patient;

f. The patient registry number of the purchaser;

g. The net weight, in grams to at least the tenth of a gram, of the Medical Marijuana prior to its placement in the Container;

h. The following warning statements:

i. "There may be health risks associated with the consumption of this product."

ii. "This marijuana's potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."

iii. "There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."

i. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana.

j. The Universal Symbol, which must be located on the front of the Container and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children."

2. Repealed.

2.1. Required Potency Statement. This subparagraph (B)(2.1) of rule M 1005 shall become effective on October 1, 2017. For each Harvest Batch of Medical Marijuana packaged within a Container, the Medical Marijuana Center shall ensure the potency of at least the Medical Marijuana's THC and CBD is included on a label that is affixed to the Container. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration for each cannabinoid listed, from every test conducted on that strain of Medical Marijuana cultivated by the same Optional Premises Cultivation Operation within the last six months. The potency shall be labeled either:

a. In a font size that is at least two font sizes larger than the surrounding label text and also not less than 10 point font, bold, and enclosed within an outlined shape such as a circle or square; or

b. Highlighted with a bright color such as yellow.

3. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Harvest Batch for microbials, mold, mildew, and filth, then a Medical Marijuana Center must ensure that a label is affixed to a Container holding any Medical Marijuana from that Harvest Batch with the following statement: **"The marijuana contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: **"The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

b. When All Required Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Harvest Batch for microbials, mold, mildew, and filth, and all the required test(s) passed, then the Container shall be labeled with the following statement: **"The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

c. Nothing in this rule permits a Medical Marijuana Business to Transfer Medical Marijuana that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

Basis and Purpose – M 1006

The statutory authority for this rule includes but is not limited to 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-402(2)(a)(I-III), 12-43.4-202(2.5)(a)(I), 12-43.3-402(2)(a), 12-43.3-402(6), 12-43.3-404(5), 12-43.3-404(10), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that the labeling on each Container holding a Medical Marijuana Infused-Product includes necessary and relevant information for consumers, does not include health and physical benefit claims, is easily accessible to consumers, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper packaging and labeling techniques for each Medical Marijuana Infused-Product because this is a public health and safety concern. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of Senate Bill 15-260. Section 1 of the bill required the State Licensing Authority to establish an acceptable potency variance for correct labeling. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

M 1006 – Packaging and Labeling of Medical Marijuana Infused-Product by a Medical Marijuana Center

A. Packaging Requirements for a Medical Marijuana Center.

1. Beginning December 1, 2016, a Medical Marijuana Center shall not purchase, take possession of, or sell Medical Marijuana-Infused Product that does not comply with rules M 604 and M 1004.5.

2. A Medical Marijuana Center must ensure that each Medical Marijuana Infused-Product is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.

3. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:

   a. If the Medical Marijuana-Infused Product is packaged in a Child-Resistant Container, a Medical Marijuana Center may defeat the Medical Marijuana-Infused Product's Child-Resistant packaging on behalf of the patient, so long as the Medical Marijuana-Infused Product remains with the packaging after the Child-Resistant properties have been defeated; or

   b. If the Medical Marijuana-Infused Product is not packaged in a Child-Resistant Container, a Medical Marijuana Center shall not be required to package the Medical Marijuana-Infused Product in a Child-Resistant Container for sale to the patient; and

   c. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.

B. Labeling of Medical Marijuana Infused-Product by a Medical Marijuana Center. Every Medical Marijuana Center must ensure that a label(s) is affixed to every Exit Package at the time of sale to a consumer that includes all of the information required by this rule. If an Exit Package is not required pursuant to subparagraph (A)(2) of this rule M 1006, and the Medical Marijuana Center elects not to provide one, then the Medical Marijuana Center must ensure the labels required by this rule are affixed to each Container of Medical Marijuana Infused-Product no later than at the time of sale to a consumer.

   1. Required Information.

      a. The license number of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer;

      b. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;

      c. The date of sale to the consumer;

      d. The patient registry number of the purchaser;

      e. The following warning statements;

         i. "There may be health risks associated with the consumption of this product."

ii. "This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."

iii. "This product was produced without regulatory oversight for health, safety, or efficacy."

iv. "There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."

f. The Universal Symbol, which must be located on the front of the Container or Exit Package as appropriate and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children.".

g. Required Potency Statement. This subsubparagraph (B)(1)(g) of rule M 1006 shall become effective October 1, 2017. Each Container holding a Medical Marijuana-Infused Product shall be labeled with the potency of at least the Medical Marijuana-Infused Product's THC and CBD. The potency shall be expressed in milligrams for each cannabinoid. The potency shall be labeled either:

i. In a font size that is at least two font sizes larger than the surrounding label text and also not less than 10 point font, bold, and enclosed within an outlined shape such as a circle or square; or

ii. Highlighted with a bright color such as yellow.

Basis and Purpose – M 1007

The statutory authority for this rule includes but is not limited to 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.4-402(2)(a)(I-III), 12-43.4-402(6), 12-43.4-404(5), 12-43.3-404(10), and 12-43.3-901(4)(b), C.R.S. The purpose of this rule is to ensure that the labeling on each Container holding a Medical Marijuana Concentrate includes necessary and relevant information for patients, does not include health and physical benefit claims, is easily accessible to patients, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques to each Medical Marijuana Concentrate as this is a public health and safety concern. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of Senate Bill 15-260. Section 1 of the bill required the State Licensing Authority to establish an acceptable potency variance for correct labeling. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

M 1007 – Packaging and Labeling of Medical Marijuana Concentrate by a Medical Marijuana Center

A. Packaging of Medical Marijuana Concentrate by a Medical Marijuana Center.

1. A Medical Marijuana Center must ensure that all Medical Marijuana Concentrate is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.

2. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:

   a. A Medical Marijuana Center shall not be required to package the Medical Marijuana Concentrate in a Child-Resistant Container for sale to the patient; and

   b. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.

   c. If the Medical Marijuana Concentrate is packaged in a Child-Resistant Container, a Medical Marijuana Center may defeat the Medical Marijuana Concentrate's Child-Resistant packaging on behalf of the patient, so long as the Medical Marijuana Concentrate remains with the packaging after the Child-Resistant properties have been defeated.

B. Labeling of Medical Marijuana Concentrate by Medical Marijuana Centers. Every Medical Marijuana Center must ensure that a label(s) is affixed to every Container holding Medical Marijuana Concentrate that includes all of the information required by this rule no later than at the time of sale to a consumer:

   1. Every Medical Marijuana Center must ensure the following information is affixed to every Container holding a Medical Marijuana Concentrate:

      a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Concentrate within the Container was grown;

      b. The license number of the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Concentrate;

      c. The Production Batch Number assigned to the Medical Marijuana Concentrate;

      d. The license number of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer;

      e. The net weight, in grams to at least the tenth of a gram, of the Medical Marijuana Concentrate prior to its placement in the Container;

      f. The date of sale to the consumer;

      g. The patient registry number of the purchaser;

      h. The following warning statements:

         i. "There may be health risks associated with the consumption of this product."

         ii. "This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."

         iv. "This product was produced without regulatory oversight for health, safety, or efficacy."

v. **"There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."**

i. The Universal Symbol, which must be located on the front of the Container and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children."

j. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Concentrate; and

k. A complete list of solvents and chemicals used to produce the Medical Marijuana Concentrate.

2. Repealed.

2.1. Required Potency Statement. This subparagraph (B)(2.1) of rule M 1007 shall become effective October 1, 2017. Each Container holding a Medical Marijuana Concentrate shall be labeled with the potency of at least the Medical Marijuana Concentrate's THC and CBD. The potency shall be expressed in milligrams for each cannabinoid. The potency shall be labeled either:

a. In a font size that is at least two font sizes larger than the surrounding label text and also not less than 10 point font, bold, and enclosed within an outlined shape such as a circle or square; or

b. Highlighted with a bright color such as yellow.

3. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed.

i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, then the Container shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package has not been tested for contaminants."** Except that when a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Food- or Water-Based Medical Marijuana Concentrate for microbials, mold, and mildew, then the Container shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Container instead shall

be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

b. When All Required Contaminant Tests Are Performed and Passed.

i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch for microbials, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501."**

c. Nothing in this rule permits a Medical Marijuana Business to Transfer Medical Marijuana Concentrate that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

M 1000-1 Series – Labeling, Packaging, and Product Safety

Effective Date. The revised Packaging, Labeling and Product Safety rules set forth in this Rule M 1000-1 Series are effective January 1, 2018, except that during the period January 1, 2018, to June 30, 2018, Licensees have the option of complying with the Rule M 1000 Series or with this Rule M 1000-1 Series, but must be fully compliant with at least one of those two Labeling, Packaging, and Product Safety Series. Beginning July 1, 2018, the Rule M 1000 Series is repealed, and compliance with this M 1000-1 Series is mandatory.

On and after July 1, 2018, all Licensees are required to package and label all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product according to the Packaging, Labeling, and Product Safety rules in this Rule M 1000-1 Series.

Basis and Purpose – M 1001-1

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(II)(A)-(B), 12-43.3-402(2)(a), 12-43.3-402(7), and 12-43.3-404(11), C.R.S. The purpose of this rule is to define minimum packaging and labeling requirements for Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product Transferred between Medical Marijuana Businesses. The State Licensing Authority finds it essential to regulate and establish labeling requirements for Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product, and that this is in the interest of the health and safety of the people of Colorado. This rule identifies information that is required on all labels to provide information necessary for the Division to regulate the cultivation, production, and sale of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. This rule also seeks to minimize, to the extent practicable, the burden of labeling compliance to Licensees. The labeling requirements in this rule apply to all Containers immediately containing Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product.

Rule M 1001-1 - Packaging and Labeling: Minimum Requirements Prior to Transfer to a Medical Marijuana Business

A. Applicability. This Rule establishes minimum requirements for packaging and labeling Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product prior to Transfer to a Medical Marijuana Business. The labeling requirements in this Rule apply to all Containers immediately containing Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product.

B. Packaging and Labeling of Medical Marijuana Flower and Trim and Medical Marijuana Concentrate Prior to Transfer to a Medical Marijuana Business. A Medical Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana flower and trim or Medical Marijuana Concentrate to another Medical Marijuana Business:

1. Packaging of Medical Marijuana Flower and Trim and Medical Marijuana Concentrate.

a. Prior to Transfer to a Medical Marijuana Business, Medical Marijuana flower and trim or Medical Marijuana Concentrate shall be placed into a Container. The Container may but is not required to be Child-Resistant.

b. Each Container of Medical Marijuana flower or trim that is Transferred to a Medical Marijuana Business shall not exceed 10 pounds of Medical Marijuana flower or trim, but may include pre-weighed units that are within the sales limit in Rule M 403(D).

c. Each Container of Medical Marijuana Concentrate that is Transferred to a Medical Marijuana Business shall not exceed 10 pounds of Medical Marijuana Concentrate, but may include pre-weighed units.

2. Labeling of Medical Marijuana Flower and Trim and Medical Marijuana Concentrate. Prior to Transfer to a Medical Marijuana Business, every Container of Medical Marijuana flower and trim or Medical Marijuana Concentrate shall be affixed with a label that includes at least the following information:

a. The license number of the Optional Premises Cultivation Operation where the Medical Marijuana was grown;

b. The Harvest Batch Number(s) assigned to the Medical Marijuana or the Production Batch Number(s) assigned to the Medical Marijuana Concentrate;

c. If applicable, the license number of the Optional Premises Cultivation Operation(s) that produced the Water-Based Medical Marijuana Concentrate;

d. If applicable, the license number of the Medical Marijuana-Infused Products Manufacturer(ers) where the Medical Marijuana Concentrate was produced;

e. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Medical Marijuana or Medical Marijuana Concentrate prior to its placement in the Container;

f. Potency test results as required to permit the receiving Medical Marijuana Business to label the Medical Marijuana or Medical Marijuana Concentrate as required by these rules; and

g. A complete list of all nonorganic Pesticides, herbicides, and fertilizers that were used in the cultivation and production of the Medical Marijuana or Medical Marijuana Concentrate.

C. Packaging and Labeling of Medical Marijuana-Infused Product Prior to Transfer to a Medical Marijuana Business. A Medical Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana-Infused Product to another Medical Marijuana Business:

1. Packaging of Medical Marijuana-Infused Product.

a. Transfer to a Medical Marijuana Business Other Than a Medical Marijuana Center. Prior to Transfer to a Medical Marijuana Business other than a Medical Marijuana Center, Medical Marijuana-Infused Product shall be placed into a Container. The Container may but is not required to be Child-Resistant.

b. Transfer to a Medical Marijuana Center. Prior to Transfer to a Medical Marijuana Center, all Medical Marijuana-Infused Product shall be packaged in a Child-Resistant Container that is ready for sale to the patient as required by the Rule M 1002-1(D)(1).

2. Labeling of Medical Marijuana-Infused Product.

a. Transfer to a Medical Marijuana Business other than a Medical Marijuana Center. Prior to Transfer to a Medical Marijuana Business other than a Medical Marijuana Center, every Container of Medical Marijuana-Infused Product shall be affixed with a label that includes at least the following information:

i. The license number of the Optional Premises Cultivation Operation(s) where the Medical Marijuana was grown;

ii. The license number of the Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana-Infused Product;

iii. The Production Batch Number(s) assigned to the Medical Marijuana-Infused Product;

iv. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Medical Marijuana-Infused Product prior to its placement in the Container;

v. Potency test results, as required to permit the receiving Medical Marijuana Business to label the Medical Marijuana-Infused Product as required by these rules; and

vi. A complete list of all nonorganic Pesticides, herbicides, and fertilizers that were used in the cultivation and production of the Medical Marijuana-Infused Product.

b. Transfer to a Medical Marijuana Center. Prior to Transfer to a Medical Marijuana Center, every Container of Medical Marijuana-Infused Product shall be affixed with a label ready for sale to the patient including all information required by Rules M 1002-1(D)(2) and 1003-1(B).

D. Packaging and Labeling of Medical Marijuana Seeds and Immature Plants Prior to Transfer to a Medical Marijuana Business. A Medical Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana seeds or Immature plants to another Medical Marijuana Business:

1. Packaging of Medical Marijuana Seeds.

   a. Prior to Transfer to a Medical Marijuana Business, Medical Marijuana seeds shall be placed into a Container. The Container may but is not required to be Child-Resistant.

   b. Each Container of Medical Marijuana seeds that is Transferred to a Medical Marijuana Business shall not exceed 10 pounds of Medical Marijuana seeds.

2. Packaging of Immature Plants. Prior to Transfer to a Medical Marijuana Business, Immature plants shall be placed into a receptacle. The receptacle may, but is not required to, be Child-Resistant.

3. Labeling of Medical Marijuana Seeds and Immature Plants. Prior to Transfer to a Medical Marijuana Business, every Container of Medical Marijuana seeds and all receptacles holding an Immature plant shall be affixed with a label that includes at least the license number of the Optional Premises Cultivation Operation where the Medical Marijuana that produced the seeds or the Immature plant was grown.

E. Prohibited Transfers – All Medical Marijuana Businesses. A Medical Marijuana Business shall not Transfer to a Medical Marijuana Center, and a Medical Marijuana Center shall not accept nor offer for sale, any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that is not packaged and labeled in conformance with the requirements of these rules, or that does not provide all information necessary to permit the Medical Marijuana Center to package and label the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product prior to Transfer to a patient. However, a Medical Marijuana Center is not required to open any tamper evident Marketing Layer received from an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer to verify the Container is Child-Resistant or labeled.

F. Shipping Containers. Licensees may Transfer multiple Containers of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product to a Medical Marijuana Business in a Shipping Container.

1. RFID Tag Required. Licensees shall ensure that either the multiple Containers placed within a Shipping Container each have an RFID tag, or the Shipping Container itself must have an RFID tag. If the Licensee elects to place the RFID tag on the Shipping Container, the Shipping Container shall contain only one Harvest Batch of Medical Marijuana, one Production Batch of Medical Marijuana Concentrate, or one Production Batch of Medical Marijuana-Infused Product. If a Shipping Container consists of more than one Harvest Batch or Production Batch, then each group of multiple Containers shall be affixed with an RFID tag. *See* Rule M 309 – Inventory Tracking System; Rule M 801 – Transport: All Medical Marijuana Businesses.

2. Labeling of Shipping Containers. Any Shipping Container that will not be displayed to the patient is not required to be labeled according to these rules.

G. Packaging and Labeling of Medical Marijuana Flower and Trim Prior to Transfer to a Medical Research Facility, a Pesticide Manufacturer or a Licensed Research Business. The packaging and labeling requirements in this M 1000-1 Series also apply to any Transfer of Medical

Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Research Facility, a Pesticide Manufacturer, or a Licensed Research Business.

H. Licensed Research Business Transfers to Persons as Part of an Approved Research Project. Any Licensed Research Business conducting research as part of an approved Research Project involving human subjects shall comply with all packaging and labeling requirements that are applicable to a Medical Marijuana Center prior to Transfer to a patient, unless the Licensed Research Business requests and receives in advance a waiver of specific packaging or labeling requirements in connection with the approved Research Project.

I. Research Transfers Prohibited. A Medical Marijuana Center shall not Transfer any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Research Facility, a Pesticide Manufacturer, or a Licensed Research Business.

J. Violation Affecting Public Safety. A violation of any rule in this M 1000-1 Series may be considered a license violation affecting public safety.

Basis and Purpose – M 1002-1

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(II)(A)-(B), 12-43.3-402(2)(a), 12-43.3-402(7), and 12-43.3-404(11), C.R.S. The purpose of this rule is to define general packaging and labeling requirements for Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product prior to Transfer to a patient. The labeling requirements in this rule apply to all Containers immediately containing Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. The State Licensing Authority finds it essential to regulate and establish labeling requirements for Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product and that this is in the interest of the health and safety of the people of Colorado. This rule identifies information that is required on all labels to provide necessary information to patients to make informed decisions and first responders in the event of accidental ingestion, over-ingestion, or allergic reaction. This rule also seeks to minimize, to the extent practicable, the burden of labeling compliance to Licensees.

Rule M 1002-1 - Packaging and Labeling: General Requirements Prior to Transfer to a Patient

A. Applicability. This Rule establishes general requirements for packaging and labeling Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product prior to Transfer to a patient. The labeling requirements in this Rule apply to all Containers immediately containing Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. The labeling requirements based on intended use in Rule M 1003-1 are in addition to, not in lieu of, the requirements in this Rule.

B. Labeling Requirements – All Medical Marijuana, Medical Marijuana Concentrate and Medical Marijuana-Infused Product.

1. Font Size. Labeling text on the Container and any Marketing Layer must be no smaller than 1/16 of an inch.

2. Labels Shall Not Be Designed to Appeal to Children. A Medical Marijuana Business shall not place any content on a Container or the Marketing Layer in a manner that reasonably appears to target individuals under the age of 21, including but not limited to, cartoon characters or similar images.

3. False or Misleading Statements. Label(s) on a Container and any Marketing Layer shall not include any false or misleading statements.

4. Trademark Infringement Prohibited. No Container or Marketing Layer shall be intentionally or knowingly labeled so as to cause a reasonable patient confusion as to whether the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product is a trademarked product or labeled in a manner that violates any federal trademark law or regulation.

5. Health and Benefit Claims. The label(s) on the Container and any Marketing Layer shall not make any claims regarding health or physical benefits to the patient.

6. Use of English Language. Labeling text on the Container and any Marketing Layer must be clearly written or printed and in the English language. In addition to the required English label, Licensees may include an additional, accurate foreign language translation on the label that otherwise complies with these rules.

7. Unobstructed and Conspicuous. Labeling text on the Container and any Marketing Layer must be unobstructed and conspicuous. A Licensee may affix multiple labels to the Container, provided that none of the information required by these rules is obstructed. For example, and not by means of limitation, labels may be accordion, expandable, extendable, or layered to permit labeling of small Containers.

8. Use of the Word “Candy” and/or “Candies” Prohibited.

    a. Licensees shall not use the word(s) “candy” and/or “candies” on the label of any Container holding Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product, or of any Marketing Layer.

    b. Notwithstanding the requirements of this subparagraph, a Medical Marijuana Business whose Identity Statement contains the word(s) “candy” and/or “candies” may place its Identity Statement on the label of the Container holding Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product, or of any Marketing Layer.

9. Child Resistant Certificate(s). A Licensee shall maintain a copy of the certificate showing that each Child-Resistant Container into which the Licensee places Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product is Child-Resistant and complies with the requirements of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995) in accordance with the requirements of Rule M 901(A).

    a. Note that this Rule does not include any later amendments or editions to the Code of Federal Regulations. The Division has maintained a copy of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995), which is available to the public for inspection and copying during the Division’s regular business hours.

10. Containers and Marketing Layers. The Container and any Marketing Layer shall have a label with all information required by this M 1000-1 Series. Any intermediary packaging between the Container and the Marketing Layer is not required to be labeled in accordance with these rules.

11. Exit Packages.

    a. Exit Packages Permitted for Child-Resistant Containers. A Medical Marijuana Center may, but is not required to, place a Child-Resistant Container into an Opaque Exit Package at the point of Transfer to the patient.

b. Exit Packages Required for Medical Marijuana Flower, Trim, and Seeds. Any Medical Marijuana flower, trim, or seeds in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient. The Exit Package is not required to be labeled but may include the Medical Marijuana Center's Identity Statement and/or Standardized Graphic Symbol.

C. Packaging and Labeling of Medical Marijuana Flower and Trim and Medical Marijuana Concentrate Prior to Transfer to a Patient. A Medical Marijuana Center shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana flower and trim or Medical Marijuana Concentrate to a patient:

1. Packaging of Medical Marijuana Flower and Trim. Prior to Transfer to a patient, Medical Marijuana flower and trim shall be in a Container that does not exceed the sales limit in Rule M 403(D). The Container may but is not required to be Child-Resistant. Any Medical Marijuana flower and trim in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient.

2. Packaging of Medical Marijuana Concentrate. Prior to Transfer to a patient, Medical Marijuana Concentrate shall be in a Child-Resistant Container. A sealed vaporizer cartridge or disposable vaporizer pen need not itself be Child-Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient.

3. Labeling of Medical Marijuana Flower and Trim and Medical Marijuana Concentrate. Prior to Transfer to a patient, every Container of Medical Marijuana flower and trim or Medical Marijuana Concentrate, and any Marketing Layer shall be affixed with a label that includes at least the following information:

a. Required License Number(s). The license number for each of the following:

i. The Optional Premises Cultivation Operation where the Medical Marijuana was grown;

ii. If applicable, the Optional Premises Cultivation Operation(s) where the Water-Based Medical Marijuana Concentrate was produced;

iii. If applicable, the Medical Marijuana-Infused Products Manufacturer where the Medical Marijuana Concentrate was produced; and

iv. The Medical Marijuana Center that sold the Medical Marijuana or Medical Marijuana Concentrate to the patient, except the Medical Marijuana Center may affix its license number to the Container or Marketing Layer.

b. Batch Numbers. The Harvest Batch Number(s) assigned to the Medical Marijuana or the Production Batch Number(s) assigned to the Medical Marijuana Concentrate.

c. Statement of Net Contents. The statement of net contents must identify the net weight of the Medical Marijuana or net weight or volume of Medical Marijuana Concentrate prior to its placement in the Container, using a standard of measure compatible with the Inventory Tracking System.

d. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than ½ of an inch by ½ of an inch, with the following

statement directly below the Universal Symbol: "**Contains Marijuana. Keep away from children."**

e. Required Potency Statement. The potency of the Medical Marijuana's or Medical Marijuana Concentrate's Total THC and CBD expressed as a percentage, which shall be displayed either:

i. In a font that is bold, and enclosed within an outlined shape such as a circle or square; or

ii. Highlighted with a bright color such as yellow.

f. Date of Sale. The Medical Marijuana Center shall affix the date of sale to the Container or Marketing layer at the point of Transfer to the patient.

g. Patient Number. The Medical Marijuana Center shall affix the patient's registration number to the Container or Marketing Layer at the time of Transfer to the patient.

h. Solvent List. A list of any solvent(s) used to produce any Solvent-Based Medical Marijuana Concentrate.

i. Nonorganic Pesticide Disclosure. A complete list of all nonorganic Pesticides, herbicides and fertilizers that were used in the cultivation and production of the Medical Marijuana or Medical Marijuana Concentrate.

j. Ingredient List Including Major Allergens. If applicable, a list of all ingredients used to manufacture the Medical Marijuana Concentrate including identification of any major allergens contained in the Medical Marijuana Concentrate in accordance with the Food Allergen Labeling and Patient Protection Act of 2004, 21 U.S.C. § 343 (2010). The Food Allergen Labeling and Patient Protection Act of 2004, 21 U.S.C. § 343 (2010) requires disclosure of the following major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

i. Note that this Rule does not include any later amendments or editions to the United States Code. The Division maintains a copy of 21 U.S.C. § 343 (2010), which is available to the public for inspection and copying during the Division's regular business hours.

k. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:

i. "**This product was produced without regulatory oversight for health, safety, or efficacy**."

ii. Testing statement identifying whether or not the product has been tested as follows:

a. If the product has been tested: "**This product complies with testing requirements**."; or

b. If the product has not been tested, "**This product has not been tested**."

iii. "**There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery**."

D. Packaging and Labeling of Medical Marijuana-Infused Product. A Medical Marijuana-Infused Products Manufacturer and a Medical Marijuana Center shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana-Infused Product:

1. Packaging of Medical Marijuana-Infused Product. Every Medical Marijuana-Infused Product shall be in a Child-Resistant Container at the time of Transfer to a Medical Marijuana Center in accordance with the following packaging limits:

a. Medical Marijuana-Infused Product Other than Edible Medical Marijuana-Infused Product. Every Medical Marijuana-Infused Product that is not Edible Medical Marijuana-Infused Product shall be placed into a Child-Resistant Container. A sealed vaporizer cartridge or disposable vaporizer pen need not itself be Child-Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient.

b. Edible Medical Marijuana-Infused Product. Every Edible Medical Marijuana-Infused Product shall be in a Child-Resistant Container. If the Edible Medical Marijuana-Infused Product contains multiple portions then it shall be placed into a Child-Resistant Container that is Resealable.

2. Labeling of Medical Marijuana-Infused Product. Prior to Transfer to a Medical Marijuana Center and a patient, every Container of Medical Marijuana-Infused Product and any Marketing Layer shall be affixed with a label that includes at least the following information:

a. Required License Number(s). The license number for each of the following:

i. The Optional Premises Cultivation Operation where the Medical Marijuana was grown;

ii. The Medical Marijuana-Infused Products Manufacturer where the Medical Marijuana-Infused Product was produced; and

iii. The Medical Marijuana Center that sold the Medical Marijuana-Infused Product to the patient, except the Medical Marijuana Center may affix its license number to the Container or Marketing Layer.

b. Batch Numbers. The Production Batch Number(s) assigned to the Medical Marijuana-Infused Product.

c. Statement of Net Contents. The statement of net contents must identify the net weight, volume, or number of Medical Marijuana-Infused Products prior to its placement in the Container, using a standard of measure compatible with the Inventory Tracking System.

d. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: "**Contains Marijuana. Keep away from children**."

e. Ingredient List Including Major Allergens. A list of all ingredients used to manufacture the Medical Marijuana-Infused Product including identification of any major allergens contained in the Medical Marijuana-Infused Product in accordance with the Food Allergen Labeling and Patient Protection Act of 2004, 21 U.S.C. § 343 (2010). The Food Allergen Labeling and Patient Protection Act of 2004, 21 U.S.C. § 343 (2010) requires disclosure of the following major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

i. Note that this Rule does not include any later amendments or editions to the United States Code. The Division maintains a copy of 21 U.S.C. § 343 (2010), which is available to the public for inspection and copying during the Division's regular business hours.

f. Required Potency Statement. The potency of the Medical Marijuana-Infused Product's active THC and CBD expressed in milligrams, which shall be displayed either:

i. In a font that is bold, and enclosed within an outlined shape such as a circle or square; or

ii. Highlighted with a bright color such as yellow.

g. Date of Sale. The Medical Marijuana Center shall affix the date of sale to the Container or Marketing layer at the point of Transfer to the patient.

h. Patient Number. The Medical Marijuana Center shall affix the patient's registration number to the Container or Marketing Layer at the time of Transfer to the patient.

i. Solvent List. A list of any solvent(s) used to produce any Solvent-Based Medical Marijuana Concentrate that is included as a production input in the Medical Marijuana-Infused Product.

j. Nonorganic Pesticide Disclosure. A complete list of all nonorganic Pesticides, herbicides and fertilizers that were used in the cultivation and production of the Medical Marijuana-Infused Product.

k. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:

i. "**This product was produced without regulatory oversight for health, safety, or efficacy**."

ii. Testing statement identifying whether or not the product has been tested as follows:

a. If the product has been tested: "**This product complies with testing requirements**."; or

b. If the product has not been tested, "**This product has not been tested.**"

iii. "**There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may**

become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery."

E. Packaging and Labeling of Seeds and Immature Plants Prior to Transfer to a Patient. A Medical Marijuana Center shall comply with the following minimum packaging and labeling requirements prior to Transferring seeds or Immature plants to a patient:

1. Packaging of Medical Marijuana Seeds. Prior to Transfer to a patient, Medical Marijuana seeds shall be in a Container. The Container may but is not required to be Child-Resistant. Any Medical Marijuana seeds in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient.

2. Packaging of Immature Plants. Prior to Transfer to a patient, Immature plants shall be placed into a receptacle. The receptacle may but is not required to be Child-Resistant.

3. Labeling of Seeds and Immature Plants. Prior to Transfer to a patient, every Container holding Medical Marijuana seeds and any receptacle containing an Immature plant must be affixed with a label that includes at least the following information:

   a. Required License Number(s). The license number for each of the following:

      i. The Optional Premises Cultivation Operation where the Medical Marijuana that produced the seeds or the Immature plant was grown; and

      ii. The Medical Marijuana Center that sold the seeds or Immature plant to the patient.

   b. Universal Symbol. The Universal Symbol on the front of the Container holding seeds and the receptacle containing each Immature plant, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: "**Contains Marijuana. Keep away from children.**"

   c. Statement of Net Contents for Seeds. A statement of net contents identifying the number of seeds in the Container.

   d. Date of Sale. The Medical Marijuana Center shall affix the date of sale to the Container or receptacle at the point of Transfer to the patient.

   e. Patient Number. The Medical Marijuana Center shall affix the patient's registration number to the Container or receptacle at the time of Transfer to the patient.

   f. Nonorganic Pesticide Disclosure. A complete list of all nonorganic Pesticides, herbicides, and fertilizers that were used in the cultivation and production of the Medical Marijuana.

   g. Required Warning Statements:

      i. "**This product was produced without regulatory oversight for health, safety, or efficacy**."

      ii. "**There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may**

become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery."

F. Permissive Information.

1. Identity Statement. A label affixed to a Container of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product, or any Marketing Layer may include, but is not required to include, the Identity Statement and/or Standardized Graphic Symbol for:

   a. The Optional Premises Cultivation Operation(s) where the Medical Marijuana was grown;

   b. The Medical Marijuana-Infused Products Manufacturer that manufactured the Medical Marijuana-Infused Product or Medical Marijuana Concentrate; and/or

   c. The Medical Marijuana Center that sold the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

2. Nutritional Fact Panel. Label(s) may include, but are not required to include, a nutritional fact panel or dietary supplement fact panel in substantial conformance with 21 CFR 101.9 (2016) or 21 C.F.R. 101.36 (2016) as follows:

   a. For Edible Medical Marijuana-Infused Products other than pills, capsules, and tinctures and Food-Based Medical Marijuana Concentrate, the nutritional fact panel shall be in substantial conformance with the requirements of 21 C.F.R. 101.9(C) (2016) which provides the FDA's nutritional labeling requirements for food;

   b. For pills, capsules, and tinctures, the dietary supplement fact panel shall be in substantial conformance with the requirements of 21 C.F.R. 101.36 (2016) which provides the FDA's nutritional labeling requirements for dietary supplements.

      i. Note that this Rule does not include any later amendments or editions to the Code of Federal Regulations. The Division maintains copies of 21 C.F.R. 101.9(C) (2016) and 21 C.F.R. 101.36 (2016), which are available to the public for inspection and copying during the Division's regular business hours.

3. Other Permissive Information. The labeling requirements in this M 1000-1 Series provide only the minimum labeling requirements. Licensees may include additional information on the label(s) so long as such information is consistent with the requirements of these rules.

Basis and Purpose – M 1003-1

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(II)(A)-(B), 12-43.3-402(2)(a), 12-43.3-402(7), and 12-43.3-404(11), C.R.S. The purpose of this rule is to define additional labeling requirements for Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product (except Medical Marijuana seeds and Immature plants) based on its intended use. These labeling requirements are in addition to, not in lieu of, the labeling requirements in Rule M 1002-1.

Rule M 1003-1 - Additional Labeling Requirements Prior to Transfer to a Patient

A. Applicability. This Rule establishes additional labeling requirements for Medical Marijuana (except seeds and Immature plants), Medical Marijuana Concentrate, and Medical Marijuana-Infused Product prior to Transfer to a patient. The labeling requirements in this Rule apply to all Containers immediately containing Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. These labeling requirements based on intended use are in addition to, not in lieu of, the requirements in Rule M 1002-1.

B. Additional Information Required on Every Container (Except Seeds and Immature Plants) Prior to Transfer to a Patient. Prior to Transfer to a patient, every Container of Medical Marijuana (excepts seeds and Immature plants), Medical Marijuana Concentrate, or Medical Marijuana-Infused Product and any Marketing Layer must have a label that includes at least the following additional information.

1. Statement of Intended Use. The Container and any Marketing Layer shall identify one or more intended use for Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product from the following exclusive list:

a. Inhaled Product:

i. Flower or Trim (including pre-rolled joint and kief);

ii. Solvent-Based Medical Marijuana Concentrate;

iii. Water-Based Medical Marijuana Concentrate;

iv. Heat/Pressure-Based Medical Marijuana Concentrate;

v. Vaporizer cartridge/vaporizer pen.

b. For Oral Consumption (Edible Medical Marijuana-Infused Product):

i. Food or drink infused with Medical Marijuana;

ii. Medical Marijuana Concentrate;

iii. Pills and capsules;

iv. Tinctures.

c. Skin and Body Products:

i. Topical;

ii. Suppository;

iii. Transdermal.

2. Inhaled Product. The label(s) on all inhaled product intended use shall also include:

a. The potency statement required by Rule M 1002-1 for: (1) flower (including pre-rolls and kief), (2) Solvent-Based Medical Marijuana Concentrate, (3) Water-Based Medical Marijuana Concentrate, (4) Heat/Pressure-Based Medical Marijuana Concentrate shall be stated as the percentage of Total THC and CBD.

b. The potency statement required by Rule M 1002-1 for vaporizer cartridges and disposable vaporizer pens shall be stated as either the percentage of Total THC and CBD, or the number of milligrams of Total THC and CBD, per cartridge or pen.

3. For Oral Consumption (Edible Medical Marijuana-Infused Products). The label(s) on all Edible Medical Marijuana-Infused Products, including but not limited to confections, liquids, Medical Marijuana-Infused foods, pills, capsules, and tinctures, shall also include:

a. Potency Statement. The potency statement required by Rule M 1002-1 shall be stated as: (1) milligrams of active THC and CBD per serving, and (2) milligrams of active THC and CBD per Container where the Container contains more than one serving.

b. Additional Warning Statement Required. The following additional warning statement shall be included on the label on the Container or Marketing Layer for all Edible Medical Marijuana-Infused Product: **"The intoxicating effects of this product may be delayed by up to 4 hours.**"

c. Expiration/Use-By Date. A product expiration date, upon which the Edible Medical Marijuana-Infused Product will no longer be fit for consumption, or a use-by-date, upon which the Edible Medical Marijuana-Infused Product will no longer be optimally fresh. Once a label with an expiration or use-by date has been affixed to a Container containing an Edible Medical Marijuana-Infused Product and any Marketing Layer, a Licensee shall not alter that expiration or use-by date, or affix a new label with a later expiration or use-by date.

d. Production Date. The date on which the Edible Medical Marijuana-Infused Product was produced which may be included in the Batch Number required by Rule M 1002-1.

e. Statement Regarding Refrigeration. If an Edible Medical Marijuana-Infused Product is perishable, a statement that the product must be refrigerated.

4. Skin and Body Products (Topical, Suppositories and Transdermal). The label(s) on all skin and body products shall also include:

a. Topical Product Potency Statement. For topical product the potency statement required by Rule M 1002-1 shall be stated as the number of milligrams of active THC and CBD per Container.

b. Suppository and Transdermal Product Potency Statement. For suppository and transdermal product, the potency statement required by Rule M 1002-1 shall be stated as the number of milligrams of active THC and CBD per suppository or transdermal, and the total number of milligrams of active THC and CBD per Container.

c. Expiration/Use-By Date. A product expiration or use-by date, after which the skin and body product will no longer be fit for use. Once a label with an expiration or use-by date has been affixed to any Container holding a skin and body product and any Marketing Layer, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date.

d. Production Date. The date on which the skin and body product was produced which may be included in the Batch Number required by Rule M 1002-1.

C. No Other Intended Use Permitted. No intended use other than those identified in this Rule shall be identified on any label. Licensees shall accurately identify all intended use(s) from the exclusive list of intended uses in this Rule on the label.

D. Multiple Intended Uses. Any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product having more than one intended use shall identify every intended use on the label and shall comply with all labeling requirements for each intended use. If there is any conflict between the labeling requirements for multiple intended uses, the most restrictive labeling requirements shall be followed. Licensees shall not counsel or advise any patient to use Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product other than in accordance with the intended use(s) identified on the label.

M 1200 Series – Enforcement

Basis and Purpose – M 1201

The statutory authority for this rule includes but is not limited to sections 12-43.3-201(4), 12-43.3-201(5), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(XX), 16-2.5-101, 16-2.5-121, and 16-2.5-124.5, C.R.S. The purpose of this rule is to allow for officers and employees of the Division to investigate all aspects of Licensees to ensure the fair, impartial, stringent, and comprehensive administration of the Medical Code and the rules promulgated pursuant to it.

M 1201 – Duties of Employees of the State Licensing Authority

A. Duties of Director

1. The State Licensing Authority may delegate an act required to be performed by the State Licensing Authority related to the day-to-day operation of the Division to the Director.

2. The Director may authorize Division employees to perform tasks delegated from the State Licensing Authority.

B. Duties of Division Investigators. The State Licensing Authority, the Department's Senior Director of Enforcement, the Director, and Division investigators shall have all the powers of any peace officer to:

1. Investigate violations or suspected violations of the Medical Code and any rules promulgated pursuant to it. Make arrests, with or without warrant, for any violation of the Medical Code, any rules promulgated pursuant to it, Article 18 of Title 18, C.R.S., any other laws or regulations pertaining to Medical Marijuana in this state, or any criminal law of this state, if, during an officer's exercise of powers or performance of duties pursuant to the Medical Code, probable cause exists that a crime related to such laws has been or is being committed;

2. Serve all warrants, summonses, subpoenas, administrative citations, notices or other processes relating to the enforcement of laws regulating Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product;

3. Assist or aid any law enforcement officer in the performance of his or her duties upon such law enforcement officer's request or the request of other local officials having jurisdiction;

4. Inspect, examine, or investigate any premises where the Licensee’s Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product are grown, stored,

cultivated, manufactured, tested, distributed, or sold, and any books and records in any way connected with any licensed activity;

5. Require any Licensee, upon demand, to permit an inspection of Licensed Premises during business hours or at any time of apparent operation, marijuana equipment, and marijuana accessories, or books and records; and, to permit the testing of or examination of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product;

6. Require Applicants to submit complete and current applications and fees and other information the Division deems necessary to make licensing decisions and approve material changes made by the Applicant or Licensee;

7. Conduct investigations into the character, criminal history, and all other relevant factors related to suitability of all Licensees and Applicants for Medical Marijuana licenses and such other Persons with a direct or indirect interest in an Applicant or Licensee, as the State Licensing Authority may require; and

8. Exercise any other power or duty authorized by law.

C. Duties of State Licensing Authority and Division Employees.

1. Employees shall maintain the confidentiality of State Licensing Authority and Division records and information. For confidentiality requirements of State Licensing Authority and Division employees who leave the employment of the State Licensing Authority, see Rule M 1308 - Confidential Information and Former State Licensing Authority Employees.

2. Pursuant to subsection 12-43.3-201(4), C.R.S., State Licensing Authority employees with regulatory oversight responsibilities for marijuana businesses licensed by the State Licensing Authority shall not work for, represent, or provide consulting services to or otherwise derive pecuniary gain from a marijuana business licensed by the State Licensing Authority or other business entity established for the primary purpose of providing services to the marijuana industry for a period of six months following his or her last day of employment with the State Licensing Authority.

3. Pursuant to subsection 12-43.3-201(5), C.R.S., disclosure of confidential records or information in violation of the provisions of the Medical Code constitutes a class 1 misdemeanor.

Basis and Purpose – M 1202

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), and 12-43.3-202(2)(a)(XX), C.R.S. This rule explains that Licensees must cooperate with Division employees when they are acting within the normal scope of their duties and that failure to do so may result in sanctions. It also explains the administrative hold process, the handling of inventory subject to administrative hold and under investigation and the process for voluntary surrender of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product.

M 1202 – Requirement for Inspections and Investigations, Searches, Administrative Holds, Voluntary Surrenders and Such Additional Activities as May Become Necessary from Time to Time

A. Applicants and Licensees Shall Cooperate with Division Employees

1. Applicants and Licensees must cooperate with employees of the Division who are conducting inspections or investigations relevant to the enforcement of laws and regulations related to the Medical Code.

2. No Applicant or Licensee shall by any means interfere with, obstruct or impede the State Licensing Authority or any employee of the Division from exercising their duties under the provisions of the Medical Code and all rules promulgated pursuant to it. This would include, but is not limited to:

    a. Threatening force or violence against an employee or investigator of the Division, or otherwise endeavoring to intimidate, obstruct, or impede employees or investigators of the Division, their supervisors, or any peace officers from exercising their duties. The term "threatening force" includes the threat of bodily harm to such individual or to a member of his or her family;

    b. Denying investigators of the Division access to premises where the Licensee's Medical Marijuana or Medical Marijuana-Infused Product are grown, stored, cultivated, manufactured, tested, distributed, or sold during business hours or times of apparent activity;

    c. Providing false or misleading statements;

    d. Providing false or misleading documents and records;

    e. Failing to timely produce requested books and records required to be maintained by the Licensee; or

    f. Failing to timely respond to any other request for information made by a Division employee or investigator in connection with an investigation of the qualifications, conduct or compliance of an Applicant or Licensee.

B. Administrative Hold

1. To prevent destruction of evidence, diversion or other threats to public safety, while permitting a Licensee to retain its inventory pending further investigation, a Division investigator may order an administrative hold of Medical Marijuana or Medical Marijuana-Infused Product pursuant to the following procedure:

    a. If during an investigation or inspection of a Licensee, a Division investigator develops reasonable grounds to believe certain Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product constitute evidence of acts in violation of the Medical Code or rules promulgated pursuant to it, or otherwise constitute a threat to the public safety, the Division investigator may issue a notice of administrative hold of any such Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. The notice of administrative hold shall provide a documented description of the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to be subject to the administrative hold and a concise statement that is promptly issued and approved by the Director or his or her designee regarding the reasons for issuing the administrative hold.

    b. Following the issuance of a notice of administrative hold, the Division will identify the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product subject to the administrative hold in the Inventory Tracking

System. The Licensee shall continue to comply with all tracking requirements. *See* Rule M 309 – Medical Marijuana Business: Inventory Tracking System.

c. The Licensee shall completely and physically segregate the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product subject to the administrative hold in a Limited Access Area of the Licensed Premises under investigation, where it shall be safeguarded by the Licensee.

d. While the administrative hold is in effect, the Licensee is prohibited from selling, giving away, Transferring, transporting, or destroying the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product subject to the administrative hold except as otherwise authorized by these Rules.

e. While the administrative hold is in effect, the Licensee must safeguard the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product subject to the administrative hold and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority. *See* Rule M 1309 Administrative Warrants.

f. Nothing herein shall prevent a Licensee from voluntarily surrendering Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that is subject to an administrative hold, except that the Licensee must follow the procedures set forth in paragraph (C) for voluntary surrender of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

g. Nothing herein shall prevent a Licensee from the continued possession, cultivation, or harvesting of the Medical Marijuana subject to the administrative hold. All Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product subject to an administrative hold must be put into separate Harvest Batches.

h. At any time after the initiation of the administrative hold, the Division may lift the administrative hold pending the administrative process, or seek other appropriate relief.

C. <u>Voluntary surrender of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product</u>

1. A Licensee, prior to a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to the Division.

a. Such voluntary surrender may require destruction of any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product in the presence of a Division investigator and at the Licensee's expense, and

b. The individual signing the Division's voluntary surrender form on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.

2. The voluntary surrender form may be utilized in connection with a stipulated agency order through which the Licensee waives the right to hearing and any associated rights.

3. The voluntary surrender form may be utilized even if the Licensee does not waive the right to hearing and any associated rights, with the understanding that the outcome of the hearing does not impact the validity of the voluntary surrender.

4. A Licensee, after a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any marijuana or marijuana product to the Division.

   a. The Licensee must complete and return the Division's voluntary surrender form within 15 calendar days of the date of the Final Agency Order.

   b. Such voluntary surrender may require destruction of any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product in the presence of a Division investigator and at the Licensee's expense.

   c. The individual signing the Division's voluntary surrender form on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.

Basis and Purpose - M 1203

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(IV), 12-43.3-202(1)(b)(XX), and 12-43.3-602, C.R.S. The purpose of this rule is to provide guidance following either an agency decision or under any circumstances where the licensee is ordered to surrender and/or destroy unauthorized Medical Marijuana, unauthorized Medical Marijuana Concentrate, and unauthorized Medical Marijuana-Infused Product. This rule also provides guidance as to the need to preserve evidence during agency investigations or subject to agency order.

M 1203 – Disposition of Unauthorized Medical Marijuana

A. After a Final Agency Order Mandates the Destruction of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. If the State Licensing Authority issues a Final Agency Order pursuant to section 12-43.3-602, C.R.S., that mandates the destruction of some or all of the Licensee's unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, the Licensee may:

   1. Voluntarily Surrender. The Licensee may voluntarily surrender to the Division all of its unauthorized Medical Marijuana, unauthorized Medical Marijuana Concentrate, or unauthorized Medical Marijuana-Infused Product that are described in the Final Agency Order in accordance with the provisions of Rule M 1202.

   2. Seek a Stay. The licensee may file a petition for a stay of the Final Agency Order with the Denver District Court within 15 days of the Final Agency Order.

   3. Take No Action. If the Licensee does not either (1) voluntarily surrender its unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product as set forth in subparagraph (A)(1) of this Rule; or (2) properly seek a stay of the Final Agency Order as set forth in subparagraph (A)(2) of this Rule, the Division will enter the Licensed Premises and seize and destroy the unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product that are the subject of the Final Agency Order.

B. General Requirements Applicable To All Licensees Following Final Agency Order To Destroy Unauthorized Medical Marijuana or Unauthorized Medical Marijuana-Infused Product. The following requirements apply regardless of whether the Licensee voluntarily surrenders its unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, seeks a stay of agency action, or takes no action:

1. The 15 day period set forth in section 12-43.3-602, C.R.S., and this rule shall include holidays and weekends.

2. During the period of time between the issuance of the Final Agency Order and the destruction of unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, the Licensee shall not Transfer, destroy, or otherwise let any unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product that are subject to the Final Agency Order leave the Licensed Premises unless specifically authorized by the State Licensing Authority or a court of competent jurisdiction.

3. During the period of time between the issuance of the Final Agency Order and the destruction of unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, the Licensee must safeguard any unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product in its possession or control and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority.

4. Unless the State Licensing Authority otherwise orders, the Licensee may cultivate, water, or otherwise care for any unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product that are subject to the Final Agency Order during the period of time between the issuance of the Final Agency Order and the destruction of the unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product.

5. If a district attorney notifies the Division that some or all of the unauthorized Medical Marijuana or Medical Marijuana-Infused Product is involved in an investigation, the Division shall not destroy the unauthorized Medical Marijuana or Medical Marijuana-Infused Product until approved by the district attorney.

M 1300 Series – Discipline

Basis and Purpose – M 1303

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), 12-43.3-202(2)(a)(XX), 24-4-104(4)(a), 12-43.3-601, and 24-4-105, C.R.S. The State Licensing Authority recognizes that if Licensees are not able to care for their products during a period of active suspension, then their plants could die, their edible products could deteriorate, and their on-hand inventory may not be properly maintained. Accordingly, this rule was written to clarify that Licensees whose licenses are summarily suspended may care for on-hand inventory, manufactured products, and plants during the suspension (unless the State Licensing Authority does not allow such activity), provided the Licensed Premises and all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product are adequately secured. In addition, the rule clarifies what activity is always prohibited during such suspension.

M 1303 – Suspension Process: Regular and Summary Suspensions

A. Signs Required During Active Suspension. Every Licensee whose License has been suspended, whether summarily or after an administrative hearing, shall post two notices in conspicuous places, one on the exterior and one on the interior of its premises, for the duration of the suspension. The notices shall at least 17 inches in length and 11 inches in width containing lettering not less 1/2" in height.

1. For suspension following issuance of a Final Agency Order, the sign shall be in the following form:

NOTICE OF SUSPENSION

MEDICAL MARIJUANA LICENSES ISSUED

FOR THESE PREMISES HAVE BEEN

SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY

FOR VIOLATION OF THE COLORADO MEDICAL MARIJUANA CODE

2. For a summary suspension pending issuance of a Final Agency Order, the sign shall be in the following form:

NOTICE OF SUSPENSION

MEDICAL MARIJUANA LICENSES ISSUED

FOR THESE PREMISES HAVE BEEN

SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY

FOR ALLEGED VIOLATION OF THE COLORADO MEDICAL MARIJUANA CODE

Any advertisement or posted signs that indicate that the premises have been closed or business suspended for any reason other than by the manner described in this rule shall be deemed a violation of these rules.

B. Prohibited Activity During Suspension

1. Unless otherwise ordered by the State Licensing Authority, during any period of suspension the Licensee shall not permit the acquisition, purchase, , serving, giving away, distribution, manufacture, sampling, testing, Transfer, or transport of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product on the Licensed Premises, nor allow patients to enter the Licensed Premises.

2. Unless otherwise ordered by the State Licensing Authority, during any period of suspension the Licensee may continue to possess, maintain, cultivate or harvest Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product on the Licensed Premises. The Licensee must fully account for all such Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product in the Inventory Tracking System. The Licensee must safeguard any Medical Marijuana or Medical Marijuana-Infused Product in its possession or control. The Licensee must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority.

C. Removal and Destruction of Medical Marijuana, Medical Marijuana Concentrate, and Marijuana-Infused Product. Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product shall not be removed from the Licensed Premises or destroyed unless and until:

1. The provisions described in section 12-43.3-602, C.R.S., related to the proper destruction of unauthorized marijuana are met, and the State Licensing Authority orders forfeiture and destruction. See also Rule M 1203 – Disposition of Unauthorized Medical Marijuana;

2. The Licensee has voluntarily surrendered the Medical Marijuana or Medical Marijuana-Infused Product in accordance with Rule M 1202(C) – Voluntary Surrender;

3. The State Licensing Authority has seized the Medical Marijuana or Medical Marijuana-Infused Product pursuant to an Administrative Warrant. See Rule M 1309 - Administrative Warrants.

D. Renewal. The issuance of a suspension or an Order of Summary Suspension does not relieve the Licensee of the obligation to timely comply with all license renewal requirements.

Basis and Purpose – M 1307

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(c), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish guidelines for enforcement and penalties that will be imposed by the State Licensing Authority for non-compliance with Medical Code, section 18-18-406.3(7), C.R.S., or any other applicable rule. The State Licensing Authority considered the type of violation and the threat of harm to the public versus purely administrative harm when setting the penalty structure. Based upon public testimony and a written commentary, Rule M 1307(A) was amended to include additional license violations affecting public safety and Rule M 1307(C.1) was added.

M 1307 – Penalties

A. Penalty Schedule. The State Licensing Authority will make determinations regarding the type of penalty to impose based on the severity of the violation in the following categories:

1. License Violations Affecting Public Safety. This category of violation is the most severe and may include, but is not limited to, Medical Marijuana sales to non-patients, consuming marijuana on the Licensed Premises, Medical Marijuana sales in excess of the relevant transaction limit, permitting the diversion of Medical Marijuana outside the regulated distribution system, possessing medical marijuana inventory or medical marijuana-infused products inventory obtained from outside the regulated distribution system or from an unauthorized source, misstatements or omissions in the Inventory Tracking System, failure to continuously escort a visitor in a Limited Access Area, violations related to co-located Medical Marijuana Businesses and Retail Marijuana Establishments, failure to maintain books and records to fully account for all transactions of the business, or packaging or labeling violations that directly impact patient safety. Violations of this nature generally have an immediate impact on the health, safety, and welfare of the public at large. The range of penalties for this category of violation may include license suspension, a fine per individual violation, a fine in lieu of suspension of up to $100,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.

2. License Violations. This category of violation is more severe than a license infraction but generally does not have an immediate impact on the health, safety and welfare of the public at large. License violations may include but are not limited to, advertising and/or marketing violations, packaging or labeling violations that do not directly impact patient safety, failure to maintain minimum security requirements, failure to keep and maintain adequate business books and records, minor or clerical errors in the inventory tracking procedures. The range of penalties for this category of violation may include a written warning, license suspension, a fine per individual violation, a fine in lieu of suspension of up to $50,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.

3. License Infractions. This category of violation is the least severe and may include, but is not limited to, failure to display required badges, unauthorized modifications of the premises of a minor nature, or failure to notify the State Licensing Authority of a minor change in ownership. The range of penalties for this category of violation may include a verbal or written warning, license suspension, a fine per individual violation, and/or a fine in lieu of suspension of up to $10,000 depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.

B. Other Factors

1. The State Licensing Authority may take into consideration any aggravating and mitigating factors surrounding the violation which could impact the type or severity of penalty imposed.

2. The penalty structure is a framework providing guidance as to the range of violations, suspension description, fines, and mitigating and aggravating factors. The circumstances surrounding any penalty imposed will be determined on a case-by-case basis.

3. For all administrative offenses involving a proposed suspension, a Licensee may petition the State Licensing Authority for permission to pay a monetary fine, within the provisions of section 12-43.3-601, C.R.S., in lieu of having its license suspended for all or part of the suspension.

C. Mitigating and Aggravating Factors. The State Licensing Authority may consider mitigating and aggravating factors when considering the imposition of a penalty. These factors may include, but are not limited to:

1. Any prior violations that the Licensee has admitted to or was found to have engaged in.

2. Good faith measures by the Licensee to prevent the violation, including the following:

   a. Proper supervision;

   b. Regularly-provided and documented employee training, provided the Licensee demonstrates all reasonable training measures were delivered prior to the Division's investigation;

   c. Standard operating procedures established prior to the Division's investigation, and which include procedures directly addressing the conduct for which imposition of a penalty is being considered; and

   d. Previously established and maintained responsible-vendor designation pursuant to Rule M 408.

3. Licensee's past history of success or failure with compliance checks.

4. Corrective action(s) taken by the Licensee related to the current violation or prior violations.

5. Willfulness and deliberateness of the violation.

6. Likelihood of reoccurrence of the violation.

7. Circumstances surrounding the violation, including, but not limited to, Licensee self-reported violation(s) of the Medical Code or rules promulgated pursuant to the Medical Code; and

8. Owner or manager is the violator or has directed an employee or other individual to violate the Medical Code or rules promulgated pursuant to the Medical Code.

M 1500 Series – Medical Marijuana Testing Program

Basis and Purpose – M 1501

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the contaminant testing and related process validation portion of the Division's Medical Marijuana sampling and testing program.

M 1501 – Medical Marijuana Testing Program – Contaminant Testing

A. Contaminant Testing Required. Unless an Optional Premises Cultivation Operation's and Medical Marijuana-Infused Products Manufacturer's cultivation or production process has achieved process validation under this Rule, it shall not Transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product unless Samples from each Harvest Batch or Production Batch from which that Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product was derived has been tested by a Medical Marijuana Testing Facility for contaminants and passed all contaminant tests required by Paragraph (C) of this Rule.

B. Process Validation and Ongoing Testing – Contaminant Testing

1. Medical Marijuana. An Optional Premises Cultivation Operation's cultivation process shall be deemed validated for contaminant testing if every Harvest Batch that it produced during at least a six-week period but no longer than a 12-week period passed all contaminant tests required by Paragraph (C) of this Rule. This must include at least six Test Batches.

2. Medical Marijuana Concentrate or Medical Marijuana Infused-Product. An Optional Premises Cultivation Operation's or a Medical Marijuana-Infused Products Manufacturer's production process shall be deemed validated regarding contaminant if every Production Batch that it produced during at least a four-week period but no longer than an eight-week period passed all contaminant tests required by paragraph (C) of this Rule. This must include at least four Test Batches.

3. Process Validation is Effective for One Year. Once an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer has successfully obtained process validation for contaminants, the process validation shall be effective for one year from the date of the last passing test required to satisfy the process validation requirements.

4. Medical Marijuana Ongoing Contaminant Testing. After successfully obtaining process validation, once every 30 days an Optional Premises Cultivation Operation shall subject at least one Harvest Batch to all contaminant testing required by Paragraph (C) of this Rule. If during any 30-day period an Optional Premises Cultivation Operation does not possess a Harvest Batch that is ready for testing, the Optional Premises Cultivation

Operation must subject its first Harvest Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Medical Marijuana. If a Harvest Batch subject to ongoing contaminant testing fails contaminant testing, the Optional Premises Cultivation Operation shall follow the procedure in Paragraph (F)(2) of this Rule. Ongoing contaminant testing pursuant to this Rule M 1501 shall be subject to the requirements in Rule M 1504. See Rule M 1504(A) – Collection of Samples.

a. The Division may reduce the frequency of ongoing contaminant testing required by Optional Premises Cultivation Operations if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.

5. Medical Marijuana Concentrate or Medical Marijuana-Infused Products Ongoing Contaminant Testing. After successfully obtaining process validation, once every 30 days an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall subject at least one Production Batch to all contaminant testing required by Paragraph (C) of this Rule. If during any 30-day period an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer does not possess a Production Batch that is ready for testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer must subject its first Production Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Medical Marijuana. If a Production Batch submitted for ongoing contaminant testing fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall follow the procedure in Paragraph (F)(2) of this Rule.

a. The Division may reduce the frequency of ongoing contaminant testing required by Optional Premises Cultivation Operations or Medical Marijuana-Infused Products Manufacturers if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.

C. Required Contaminant Tests.

1. Microbial Contaminant Testing. Harvest Batches of Medical Marijuana and Production Batches of Water, Heat/Pressure-, or Food-Based Medical Marijuana Concentrate and Medical Marijuana-Infused Product must be tested for microbial contamination by a Medical Marijuana Testing Facility at the frequency established by Paragraphs (A) and (B) of this Rule. The microbial contamination test must include, but need not be limited to, testing to determine the presence of Salmonella sp. and shiga-toxin producing Escherichia coli., and the amount of total yeast and mold.

2. Repealed.

3. Residual Solvent Contaminant Testing. Production Batches of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana-Infused Products Manufacturer must be tested for residual solvent contamination by a Medical Marijuana Testing Facility at the frequency established by Paragraphs (A) and (B) of this Rule. The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of acetone, butane, ethanol, heptanes, isopropyl alcohol, propane, benzene*, toluene*, pentane, hexane*, and total xylenes (m, p, o –

xylenes)*. * Note: These solvents are not approved for use. Testing is required for these solvents due to their possible presence in the solvents approved for use per Rule M 605.

4. Mycotoxin Contaminant Testing. As part of Remediation, each Production Batch of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana-Infused Products Manufacturer from Medical Marijuana that failed microbial contaminant testing produced must be tested by a Retail Marijuana Testing Facility for mycotoxin contamination. The mycotoxin contaminant test must include, but need not be limited to, testing to determine the presence of, and amounts present of, aflatoxins (B1, B2, G1, and G2) and ochratoxin A. This is in addition to all other contaminant testing required by this Paragraph (C).

5. Pesticide Contaminant Testing. Harvest Batches of Medical Marijuana must be tested for Pesticide contamination by a Medical Marijuana Testing Facility at the frequency established by this Rule 1501(A) and (B). The Pesticide contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, the Pesticides listed in Rule M 712(E)(5).

D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer Transferring, or processing into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch. Additional tests may include, but need not be limited to, screening for Pesticide, chemical contaminants or other types of biological contaminants, microbials, molds, metals, or residual solvents.

E. Exemptions

1. Medical Marijuana Concentrate. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from this Rule if the Medical Marijuana-Infused Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Medical Marijuana-Infused Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing. The manufactured Medical Marijuana-Infused Product shall be subject to mandatory testing under this Rule.

F. Required Re-Validation - Contaminants.

1. Material Change Re-validation. If an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer makes a Material Change to its cultivation or production process or its standard operating procedure manual, then it must have the first five Harvest Batches or Production Batches produced using the procedures tested for all of the contaminants required by Paragraph (C) of this Rule regardless of whether its process has been previously validated regarding contaminants. If any of those tests fail, then the Medical Marijuana Business's process must be re-validated.

   a. Pesticide. It shall be considered a Material Change if an Optional Premises Cultivation begins using a new or different Pesticide during its cultivation process.

   b. Solvents. It shall be considered a Material Change if a Medical Marijuana-Infused Products Manufacturer begins using a new or different solvent or combination of solvents or changes any parameters for equipment related to the solvent purging process, including but not limited to, time, temperature, or pressure.

c. Cultivation. It shall be considered a Material Change if an Optional Premises Cultivation Operation begins using a new or different method for any material part of the cultivation process, including but not limited to, changing from one growing medium to another.

d. Notification. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer must notify the Medical Marijuana Testing Facility of the Material Change.

e. Testing Required Prior to Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this Rule, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced it may not Transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any of the Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch.

2. Failed Contaminant Testing and Re-Validation. Failed contaminant testing may constitute a violation of these rules. Additionally, if a Sample the Division requires to be tested fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall follow the procedures in Rule M 1507(B) for any Inventory Tracking System package, Harvest Batch, or Production Batch from which the failed Sample was taken. The Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall also submit three additional Test Batches of the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product for contaminant testing by a Medical Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall re-validate its process for contaminants.

3. Repealed.

G. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose – M 1502

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the mandatory testing portion of the Division's Medical Marijuana sampling and testing program.

M 1502 – Medical Marijuana Testing Program – Mandatory Testing

A. Required Sample Submission. A Medical Marijuana Business may be required by the Division to submit a Sample(s) of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product it possesses to a Medical Marijuana Testing Facility at any time regardless of whether its process has been validated and without notice.

1. Samples collected pursuant to this Rule may be tested for potency or contaminants which may include, but may not be limited to, Pesticide, microbials, mycotoxin, molds, metals, residual solvents, biological contaminants, and chemical contaminants.

2. When a Sample(s) is required to be submitted for testing, the Medical Marijuana Business may not Transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from the Inventory Tracking System package, Harvest Batch or Production Batch from which the Sample was taken, unless or until it passes all required testing.

B. Methods for Determining Required Testing.

1. Random Testing. The Division may require Samples to be submitted for testing through any one or more of the following processes: random process, risk-based process or other internally developed process, regardless of whether a Medical Marijuana Business's process has been validated.

2. Inspection or Enforcement Tests. In addition, the Division may require a Medical Marijuana Business to submit a Sample for testing if the Division has reasonable grounds to believe that:

a. Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product is contaminated or mislabeled;

b. A Medical Marijuana Business is in violation of any product safety, health or sanitary statute, rule or regulation; or

c. The results of a test would further an investigation by the Division into a violation of any statute, rule or regulation.

3. Beta Testing. The Division may require a Medical Marijuana Business to submit Samples from certain randomly selected Harvest Batches or Production Batches for potency or contaminant testing prior to implementing mandatory testing.

C. Minimum Testing Standards. The testing requirements contained in the M 1500 series are the minimum required testing standards. Medical Marijuana Businesses are responsible for ensuring adequate testing on any Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana Infused-Products they produce or Transfer to ensure safety for human consumption.

D. Additional Sample Types. The Division may also require a Medical Marijuana Business to submit Samples comprised of items other than Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to be tested for contaminants which may include, but may not be limited to, Pesticide, microbials, molds, metals, residual solvents, biological contaminants, and chemical contaminants. The following is a non-exhaustive list of the types of Samples that may be required to be submitted for contaminant testing:

1. Specific Medical Marijuana plant(s) or any portion of a Medical Marijuana plant(s),

2. Any growing medium, water or other substance used in the cultivation process,

3. Any water, solvent or other substance used in the processing of a Medical Marijuana Concentrate,

4. Any ingredient or substance used in the manufacturing of a Medical Marijuana-Infused Product; or

5. Swab of any equipment or surface.

E. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose – M 1503

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the potency testing and related process validation portion of the Division's Medical Marijuana sampling and testing program.

M 1503 – Medical Marijuana Testing Program – Potency Testing

Rule M 1503 shall be effective beginning July 1, 2016.

A. Potency Testing – General.

1. Test Batches. A Test Batch submitted for potency testing may only be comprised of Samples that are of the same strain of Medical Marijuana or from the same Production Batch of Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

2. Cannabinoid Profile. A potency test conducted pursuant to this rule must at least determine the level of concentration of THC, THCA, CBD, CBDA and CBN.

B. Potency Testing for Medical Marijuana.

1. Initial Potency Testing. An Optional Premises Cultivation Operation must have potency tests conducted by a Medical Marijuana Testing Facility on four Harvest Batches, created a minimum of one week apart, for each strain of Medical Marijuana that it cultivates.

a. The first potency test must be conducted on each strain prior to the Optional Premises Cultivation Operation Transferring or processing into a Medical Marijuana Concentrate any Medical Marijuana of that strain.

b. All four potency tests must be conducted on each strain no later than December 1, 2016 or six months after the Optional Premises Cultivation Operation begins cultivating that strain, whichever is later.

2. Ongoing Potency Testing. After the initial four potency tests, an Optional Premises Cultivation Operation shall have each strain of Medical Marijuana that it cultivates tested for potency at least once per quarter.

C. Potency Testing for Medical Marijuana Concentrate. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer must have a potency test conducted by a Medical Marijuana Testing Facility on every Production Batch of Medical Marijuana Concentrate that it produces prior to Transferring or processing into a Medical Marijuana-Infused Product any of the Medical Marijuana Concentrate from that Production Batch.

D. Potency Testing for Medical Marijuana-Infused Product

1. Potency Testing Required for Medical Marijuana-Marijuana Infused Product. A Medical Marijuana-Infused Products Manufacturer shall have potency tests conducted by a Medical Marijuana Testing Facility on every Production Batch of each type of Medical Marijuana Infused-Product that it produces prior to Transferring any of the Medical Marijuana-Infused Product from that Production Batch, unless the Medical Marijuana-

Infused Products Manufacturer has successfully completed process validation for potency and homogeneity for the particular type of Medical Marijuana-Infused Product.

2. Required Tests. Potency and homogeneity tests conducted on Medical Marijuana-Infused Product must determine the level of concentration of the required Cannabinoids and whether or not THC is homogeneously distributed throughout the product.

3. Partially Infused Medical Marijuana-Infused Products. If only a portion of a Medical Marijuana-Infused Product is infused with Medical Marijuana, then the Medical Marijuana-Infused Products Manufacturer must inform the Medical Marijuana Testing Facility of exactly which portions of the Medical Marijuana-Infused Product are infused and which portions are not infused.

E. Process Validation of - Potency and Homogeneity.

1. A Medical Marijuana-Infused Products Manufacturer may process validate potency and homogeneity for each type of non-Edible Medical Marijuana-Infused Product and each type of Edible Medical Marijuana-Infused Product that it manufactures so long as the Edible Medical Marijuana-Infused Product contains 100 milligrams or less of THC.

2. A Medical Marijuana-Infused Products Manufacturer's production process for a particular type of Medical Marijuana-Infused Product shall be deemed valid regarding potency and homogeneity if every Production Batch that it produces for that particular type of Medical Marijuana-Infused Product during at least a four-week period but no longer than an eight-week period passes all potency and homogeneity tests required by Rule M 1503(D)(2). This must include at least four Test Batches.

3. Expiration of Process Validation. A Medical Marijuana-Infused Products Manufacturer shall be required to re-validate its process every 12 months from the date process validation is achieved, after which point the process validation expires. If the process validation expires, the Medical Marijuana-Infused Products Manufacturer shall comply with the requirements of Paragraph (D)(1) of this Rule.

4. Medical Marijuana-Infused Product Ongoing Potency and Homogeneity Testing. After successfully obtaining process validation, once per quarter a Medical Marijuana-Infused Products Manufacturer shall subject at least one Production Batch of each type of Medical Marijuana-Infused Product that it produces to potency and homogeneity testing required by Paragraph (D) of this Rule. If during any quarter a Medical Marijuana-Infused Products Manufacturer does not possess a Production Batch that is ready for testing, the Medical Marijuana-Infused Products Manufacturer must subject its first Production Batch that is ready for testing to the required potency and homogeneity testing prior to Transfer or processing of the Medical Marijuana. If a Test Batch submitted for ongoing potency and homogeneity testing fails potency and homogeneity testing, the Medical Marijuana-Infused Products Manufacturer shall follow the procedure in Paragraph (F)(2) of this Rule. Ongoing potency and homogeneity testing pursuant to this Rule M 1503 shall be subject to the requirements in Rule M 1504. See Rule M 1504(A) – Collection of Samples.

a. The Division may reduce the frequency of ongoing potency and homogeneity testing required by Medical Marijuana-Infused Products Manufacturer if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing potency and homogeneity testing to the Licensee's last electronic mailing address provided to the Division.

F. Required Re-Validation - Potency and Homogeneity - Medical Marijuana-Infused Product.

1. Material Change Re-Validation. If a Medical Marijuana-Infused Products Manufacturer elects to process validate any Medical Marijuana-Infused Product for potency and homogeneity and it makes a Material Change to its production process for that particular type of Medical Marijuana-Infused Product, then the Medical Marijuana-Infused Products Manufacturer must re-validate the production process.

   a. New Equipment. It shall be considered a Material Change if the Medical Marijuana-Infused Products Manufacturer begins using new or different equipment for any material part of the production process.

   b. Notification. A Medical Marijuana-Infused Product Manufacturer must notify the Medical Marijuana Testing Facility of a Material Change.

   c. Testing Required Prior to Transfer. When a Production Batch is required to be submitted for testing pursuant to this Rule, the Medical Marijuana-Infused Product Manufacturer that produced it may not Transfer Medical Marijuana Product from that Production Batch unless or until it obtains a passing test.

2. Failed Potency Testing Re-Validation. If a Sample the Division requires to be tested fails potency testing, the Medical Marijuana-Infused Products Manufacturer shall follow the procedures in Rule M 1507(C) for any Inventory Tracking System package or Production Batch associated with the failed Sample. The Medical Marijuana-Infused Products Manufacturer shall also submit three additional Test Batches of the Medical Marijuana-Infused Product for potency testing by a Medical Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails potency testing, the Medical Marijuana-Infused Products Manufacturer shall re-validate its process for potency.

F. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose – M 1504

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing sampling procedures and rules for the Division's Medical Marijuana sampling and testing program.

M 1504 – Medical Marijuana Testing Program – Sampling Procedures

A. Collection of Samples

1. Sample Collection. All Samples submitted for testing pursuant to this rule must be collected by Division representatives or in accordance with the Division's sampling policy which is found in the Colorado Department of Public Health and Environment Reference Library at https://tinyurl.com/y8p86vu3. This Reference Library may be continuously updated as new materials become available in accordance with section 25-1.5-106(3.5)(d), C.R.S..

2. Sample Selection. The Division may elect, at its sole direction, to assign Division representatives to collect Samples, or may otherwise direct Sample selection, including,

but not limited to, through Division designation of a Harvest Batch or Production Batch in the Inventory Tracking System from which a Medical Marijuana Business shall select Samples for testing. A Medical Marijuana Business, its Owners and employees shall not attempt to influence the Samples selected by Division personnel. If the Division does not select the Harvest Batch or Production Batch to be tested, a Medical Marijuana Business must collect and submit Sample(s) that are representative of the Harvest Batch or Production Batch being tested.

3. Adulteration or Alteration Prohibited. A Licensee or its agent shall not adulterate or alter, or attempt to adulterate or alter, any Samples of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product for the purpose of circumventing contaminant testing detection limits or potency testing requirements. The Sample(s) collected and submitted for testing must be representative of the Harvest Batch or Production Batch being tested. A violation of this Paragraph (A)(3) shall be considered a license violation affecting public safety.

B. Minimum Number of Samples Per Test Batch Submission. These sampling rules shall apply until such time as the State Licensing Authority revises these rules to implement a statistical sampling model. Each Test Batch of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product submitted for testing must be comprised of a representative selection of Samples. Unless a greater amount is required to comply with these rules, each each Test Batch of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product must be comprised of at least the following number of separately taken Samples, which may be submitted for testing in all required testing categories:

1. Samples for Test Batches of Medical Marijuana.

   a. For Harvest Batches weighing up to 10 pounds, a minimum of eight separate 0.5 gram Samples must be submitted as one Test Batch.

   b. For Harvest Batches or Production Batches weighing more than 10 pounds but less than 20 pounds, a minimum of 12 separate 0.5 gram Samples must be submitted as one Test Batch.

   c. For Harvest Batches weighing 20 pounds or more but less than 30 pounds, a minimum of 15 separate 0.5 gram Samples must be submitted as one Test Batch.

   d. For Harvest Batches weighing 30 pound or more but less than 40 pounds, a minimum of 18 separate 0.5 gram Samples must be submitted as one Test Batch.

   e. For Harvest Batches weighing 40 pounds or more but less than 100 pounds, a minimum of 23 separate 0.5 gram Samples must be submitted as one Test Batch.

   f. For Harvest Batches weighing 100 pounds or more, a minimum of 29 separate 0.5 gram Samples must be submitted as one Test Batch.

2. Repealed.

3. Samples for Test Batches of Medical Marijuana Concentrate.

   a. For Production Batches weighing up to one pound, a minimum of eight separate 0.5 gram Samples must be submitted as one Test Batch.

b. For Production Batches weighing more than one pound and less than two pounds, a minimum of 12 separate 0.5 gram Samples must be submitted as one Test Batch.

c. For Production Batches weighing two pounds or more but less than three pounds, a minimum of 15 separate 0.5 gram Samples must be submitted as one Test Batch.

d. For Production Batches weighing three pounds or more but less than four pounds, a minimum of 18 separate 0.5 gram Samples must be submitted as one Test Batch.

e. For Production Batches weighing four pounds or more but less than 10 pounds, a minimum of 23 separate 0.5 gram Samples must be submitted as one Test Batch.

f. For Production Batches weighing 10 pounds or more, a minimum of 29 separate 0.5 gram Samples must be submitted as one Test Batch.

4. Samples for Test Batches of Medical Marijuana-Infused Product. A Sample of Medical Marijuana-Infused Product must be packaged for sale prior to Transfer to a Medical Marijuana Testing Facility. Each such package of Medical Marijuana-Infused Product shall constitute one Sample.

a. For Production Batches of up to 100 Samples, a minimum of two separate Samples must be submitted as one Test Batch.

b. For Production Batches of up to 500 Samples, a minimum of four separate Samples must be submitted as one Test Batch.

c. For Production Batches of up to 1000 Samples, a minimum of six separate Samples must be submitted as one Test Batch.

d. For Production Batches of up to 5000 Samples, a minimum of eight separate Samples must be submitted as one Test Batch.

e. For Production Batches of up to 10,000 Samples, a minimum of 10 Samples must be submitted as one Test Batch.

f. For Production Batches of more than 10,000 Samples, a minimum 12 Samples must be submitted as one Test Batch.

C. Repealed.

D. Medical Marijuana Testing Facility Selection. The Division will generally permit a Medical Marijuana Business to select which Medical Marijuana Testing Facility will test a Sample collected pursuant to this rule. However, the Division may elect, at is sole discretion, to assign a Medical Marijuana Testing Facility to test the Sample.

E. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

M 1505 – Medical Marijuana Testing Program – Test Batches - Repealed

Basis and Purpose – M 1507

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing rules governing the quarantining of potentially contaminated product and the destruction of product that failed contaminant or potency testing for the Division's Medical Marijuana sampling and testing program.

M 1507 – Medical Marijuana Testing Program – Contaminated Product and Failed Test Results

A. Quarantining of Product.

1. If the Division has reasonable grounds to believe that a particular Harvest Batch, Production Batch, or Inventory Tracking System package of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product is contaminated or presents a risk to public safety, then the Division may require a Medical Marijuana Business to quarantine it until the completion of the Division's investigation, which may include, but is not limited to, the receipt of any test results.

2. If a Medical Marijuana Business is notified by any local or state agency, or by a Medical Marijuana Testing Facility, that a Test Batch failed a contaminant or potency test, then the Medical Marijuana Business shall quarantine any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from any Inventory Tracking System package, Harvest Batch or Production Batch associated with that failed Test Batch and must follow the procedures established pursuant to paragraphs (B), (B.1), (B.2), and/or (C) of this Rule.

3. Except as provided by this Rule, Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product that has been quarantined pursuant to this Rule must be physically separated from all other inventory and the Licensee may not Transfer or further process the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

4. In addition to any other method authorized by law, the Division may implement the quarantine through the Inventory Tracking System by (a) indicating failed test results and (b) limiting the Licensee's ability to Transfer the quarantined Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product unless otherwise permitted by these rules.

B. Failed Contaminant Testing: All Contaminant Testing Except Microbial Testing of Medical Marijuana Flower or Trim and Pesticide Testing. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch failed contaminant testing (except microbial testing of Medical Marijuana flower or trim and Pesticide testing), then for each Inventory Tracking System package, Harvest Batch or Production Batch associated with that failed Test Batch the Medical Marijuana Business must either:

1. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch or Production Batch pursuant to Rule M 307 – Waste Disposal; or

2. Decontaminate the Inventory Tracking System package, Harvest Batch or Production Batch, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the required contaminant test that failed. Unless at least one of the two retests is conducted by the same Medical Marijuana Testing Facility that reported the original failed test result, the two retests must

be performed by two different Medical Marijuana Testing Facilities. Such testing must comport with the sampling procedures under Rule M 1504.

a. If both new Test Batches pass the required contaminant testing, then the Inventory Tracking System package, Harvest Batch or Production Batch of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product associated with each Test Batch may be Transferred or processed into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

b. If one or both of the Test Batches do not pass contaminant testing, then the Medical Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch or Production Batch included in that Test Batch pursuant to Rule M 307 – Waste Disposal.

B.1. Failed Contaminant Testing: Microbial Testing of Medical Marijuana Flower or Trim. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch of Medical Marijuana flower or trim failed microbial testing, then for each Inventory Tracking System package or Harvest Batch associated with that failed Test Batch the Medical Marijuana Business must either:

1. Destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule M 307 – Waste Disposal;

2. Decontaminate the Inventory Tracking System package or Harvest Batch of Medical Marijuana flower or trim, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the required microbial test that failed. Unless at least one of the two retests is conducted by the same Medical Marijuana Testing Facility that reported the original failed test result, the two retests must be performed by two different Medical Marijuana Testing Facilities. Such testing must comport with the sampling procedures under Rule M 1504.

   a. If both Test Batches pass the required microbial testing, then the Inventory Tracking System package or Harvest Batch of Medical Marijuana flower or trim associated with each Test Batch may be Transferred or processed into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

   b. If one or both of the Test Batches do not pass microbial testing, then the Medical Marijuana Business must either: (i) destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule M 307 – Waste Disposal; or (ii) Transfer the Inventory Tracking System package or Harvest Batch for Remediation pursuant to Paragraph (B.1)(3)(b) below.

3. In lieu of decontamination pursuant Paragraph (B.1)(2) above, the Medical Marijuana Business may transfer all Inventory Tracking System packages or Harvest Batches associated with that failed Test Batch to a Medical Marijuana-Infused Products Manufacturer for decontamination and/or Remediation by the Medical Marijuana-Infused Products Manufacturer.

   a. Decontamination. Only if the Medical Marijuana Business has not already attempted to decontaminate pursuant to Paragraph (B.1)(2) above, the Medical Marijuana-Infused Products Manufacturer may decontaminate the Inventory Tracking System package or Harvest Batch of Medical Marijuana flower or trim, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the required microbial test that failed. Unless at least one of the two retests is conducted by the same

Medical Marijuana Testing Facility that reported the original failed test result, the two retests must be performed by two different Medical Marijuana Testing Facilities. Such testing must comport with the sampling procedures under Rule M 1504.

i. If both Test Batches pass the required microbial testing, then the Inventory Tracking System package or Harvest Batch of Medical Marijuana flower or trim associated with each Test Batch may be Transferred or processed into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

ii. If one or both of the Test Batches do not pass microbial testing, then the Medical Marijuana Business must either: (i) destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule M 307 – Waste Disposal; or (ii) attempt Remediation of the Inventory Tracking System package or Harvest Batch for Remediation pursuant to Paragraph (B.1)(3)(b) below.

b. Remediation.

i. For Remediation, the Medical Marijuana Business shall process the Inventory Tracking System package or Harvest Batch of Medical Marijuana flower or trim associated with the failed Test Batch into a Solvent-Based Medical Marijuana Concentrate. No other Medical Marijuana shall be included in the Solvent-Based Medical Marijuana Concentrate.

ii. The Solvent-Based Medical Marijuana Concentrate that was manufactured pursuant to Paragraph (B.1)(3)(b) shall undergo all required contaminant testing pursuant to Rule M 1501(C) – Medical Marijuana Testing Program – Contaminant Testing, potency testing pursuant to Rule M 1503 – Medical Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Medical Marijuana Code or these rules, including but not limited to mycotoxins. Such testing must comport with the sampling procedures under Rule M 1504.

iii. If the Solvent-Based Medical Marijuana Concentrate that was manufactured pursuant to Paragraph (B.1)(3)(b) fails contaminant testing, the Medical Marijuana Business shall destroy and document the destruction of the Inventory Tracking System package(s) or Production Batch(es) of Solvent-Based Medical Marijuana Concentrate pursuant to Rule M 307 – Waste Disposal.

c. Repealed.

B.2. Failed Contaminant Testing: Pesticide Testing. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch failed Pesticide testing, then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated with that failed Test Batch the Medical Marijuana Business must either:

1. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch or Production Batch pursuant to Rule M 307 – Waste Disposal; or

2. Request that the Medical Marijuana Testing Facility that reported the original fail conduct two additional analyses of the original Test Batch submitted in accordance with Rule M 1504.

   a. If both retesting analyses pass the required Pesticide testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-infused Product may be Transferred or processed into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

   b. If one or both of the retesting analyses do not pass Pesticide testing, then the Medical Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule M 307 – Waste Disposal.

C. Failed Potency Testing. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch of Medical Marijuana-Infused Product failed potency testing, then for each Inventory Tracking System package or Production Batch associated with that failed Test Batch the Medical Marijuana Business must either:

1. Destroy and document the destruction of the Inventory Tracking System package or Production Batch pursuant to Rule M 307 – Waste Disposal; or

2. Attempt corrective measures, if possible, and create two new Test Batches each containing the requisite number of Samples, and have those Test Batches tested for the required potency test that failed. Unless at least one of the two retests is conducted by the same Medical Marijuana Testing Facility that reported the original failed test result, the two retests must be performed by two different Medical Marijuana Testing Facilities. Such testing must comport with the sampling procedures under Rule M 1504.

   a. If both new Test Batches pass potency testing, then any the Inventory Tracking System package or Production Batch associated with the Test Batch may be Transferred.

   b. If one or both of the Test Batches do not pass potency testing, then the Medical Marijuana-Infused Products Manufacturer must destroy and document the destruction of the Inventory Tracking System package or Production Batch pursuant to Rule M 307 – Waste Disposal.

D. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

M 1600 Series – Medical Marijuana Transporters

Basis and Purpose – M 1602

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), and 12-43.3-406, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by a Medical Marijuana Transporter.

M 1602 – Medical Marijuana Transporter: General Limitations or Prohibited Acts

A. Sales, Liens, and Secured Interests Prohibited. A Medical Marijuana Transporter is prohibited from buying, selling, or giving away Medical Marijuana, Medical Marijuana Concentrate, or

Medical Marijuana-Infused Product, or from receiving complimentary Medical Marijuana. Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. A Medical Marijuana Transporter shall not place or hold a lien or secured interest on Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

B. Licensed Premises Permitted. A Medical Marijuana Transporter shall maintain a Licensed Premises if it: (1) temporarily stores any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product, or (2) modifies any information in the Inventory Tracking System generated transport manifest. The Licensed Premises shall be in a local jurisdiction that authorizes the operation of Medical Marijuana Centers. If a Medical Marijuana Transporter Licensed Premises is co-located with a Retail Marijuana Transporter Licensed Premises, then the combined Licensed Premises shall be in a local jurisdiction that authorizes the operation of both Medical Marijuana Centers and Retail Marijuana Stores.

C. Off-Premises Storage Permit. A Medical Marijuana Transporter may maintain one or more permitted off-premises storage facilities. See Rule M 802 – Off-Premises Storage of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product: All Medical Marijuana Businesses.

D. Storage Duration. A Medical Marijuana Transporter shall not store Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product for longer than 7 days from receiving it at its Licensed Premises or off-premises storage facility. The total allowable 7 day storage duration begins and applies regardless of which of the Medical Marijuana Transporter's premises receives the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product first, (ie. the Medical Marijuana Transporter's Licensed Premises, or any of its off-premises storage facilities).

E. Control of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. A Medical Marijuana Transporter is responsible for the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product once it takes control of the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product and until the Medical Marijuana Transporter delivers it to the receiving Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer.. For purposes of this rule, taking control of the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product means removing it from the originating Medical Marijuana Business's Licensed Premises and placing the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product in the transport vehicle.

F. Location of Orders Taken and Delivered. A Medical Marijuana Transporter is permitted to take orders on the Licensed Premises of any Medical Marijuana Business to transport Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. The Medical Marijuana Transporter shall deliver the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product to the Licensed Premises of a licensed Medical Marijuana Business, a Medical Research Facility, or Pesticide Manufacturer.

G. Consumption Prohibited. A Licensee shall not permit the consumption of marijuana or marijuana product on Licensed Premises or in transport vehicles.

H. A Medical Marijuana Transporter shall receive Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product from the originating Licensee packaged in the way that it is intended to be delivered to the final destination Licensee, Medical Research Facility, or Pesticide Manufacturer. The Medical Marijuana Transporter shall deliver the Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product in the same, unaltered packaging to the final destination Licensee.

I. Opening of Sealed Packages or Containers and Re-Packaging Prohibited. A Medical Marijuana Transporter shall not open Containers of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product. Medical Marijuana Transporters are prohibited from re-packaging Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

J. Temperature-Controlled Transport Vehicles. A Medical Marijuana Transporter shall utilize temperature-controlled transport vehicles when necessary to prevent spoilage of the transported Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product.

K. Damaged or Refused Product. Any damaged Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that is undeliverable to the final destination Medical Marijuana Business, or any Medical Marijuana or Medical Marijuana-Infused Product that is refused by the final destination Medical Marijuana Business shall be transported back to the originating Medical Marijuana Business.

L. Transport of Medical Marijuana Vegetative Plants Authorized. Medical Marijuana Vegetative plants may only be transported between Licensed Premises and such transport shall only be permitted due to an approved change of location pursuant to Rule M 206 or due to a one-time transfer pursuant to Rule M 211. Transportation of Vegetative plants to a permitted off-premises storage facility shall not be allowed. This restriction shall not apply to Immature plants.

Basis and Purpose – M 1603

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XVIII.6), 12-43.3-202(2)(a)(XX), and 12-43.3-406(3) C.R.S. The purpose of this rule is to establish a Medical Marijuana Transporter's obligation to account for and track all Medical Marijuana. Medical Marijuana Concentrate, and Medical Marijuana-Infused Product on the Licensed Premises from the point they are transferred from the originating Medical Marijuana Business to the destination Medical Marijuana Business.

M 1603 – Medical Marijuana Transporter: Inventory Tracking System

A. Minimum Tracking Requirement. A Medical Marijuana Transporter must use the Inventory Tracking System to ensure its transported Medical Marijuana. Medical Marijuana Concentrate, and Medical Marijuana-Infused Product are identified and tracked from the point they are transferred from a Medical Marijuana Business when the Medical Marijuana Transporter takes control of the Medical Marijuana. Medical Marijuana Concentrate, and Medical Marijuana-Infused Product by removing it from the originating Medical Marijuana Business's Licensed Premises and placing the Medical Marijuana. Medical Marijuana Concentrate, and Medical Marijuana-Infused Product in the Medical Marijuana Transporter's transport vehicle, through delivery to the destination Medical Marijuana Business, Medical Research Facility, or Pesticide Manufacturer. See also Rule R 309 –Inventory Tracking System. A Medical Marijuana Transporter must have the ability to reconcile its transported Medical Marijuana. Medical Marijuana Concentrate, and Medical Marijuana-Infused Product with the Inventory Tracking System and the associated transaction history and transportation order receipts. See also Rule M 901 – Business Records Required.

1. A Medical Marijuana Transporter is prohibited from accepting any Medical Marijuana. Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from another Medical Marijuana Business without receiving a valid transport manifest generated from the Inventory Tracking System.

2. A Medical Marijuana Transporter must immediately input all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product received at its Licensed

Premises or off-premises storage facility, accounting for all RFID tags, into the Inventory Tracking System at the time of receipt of the Medical Marijuana. Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

3. A Medical Marijuana Transporter must reconcile transactions to the Inventory Tracking System at the close of business each day.

4. All information on the Inventory Tracking System generated transport manifests must be accurate.

M 1800 Series – Medical Marijuana Transfers to Unlicensed Medical Research Facilities and Pesticide Manufacturers

Basis and Purpose - M 1801

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b) 12-43.3-202(1)(h)(I), and 25-1.5-106.5, C.R.S. The purpose of this rule is to establish requirements associated with the Transfer of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product to Medical Research Facilities, including requirements for the possession and disposition of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product by Medical Research Facilities.

M 1801 – Medical Research Facilities

A. Transfers to Medical Research Facilities. An Optional Premises Cultivation Operation may Transfer Medical Marijuana or Medical Marijuana Concentrate to a Medical Research Facility pursuant to Rule M 501. A Medical Marijuana-Infused Products Manufacturer may Transfer Medical Marijuana-Infused Product and Medical Marijuana Concentrate to a Medical Research Facility pursuant to Rule M 601.

B. Agreement with Medical Research Facility. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that Transfers Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Research Facility shall enter into a written agreement with the Medical Research Facility prior to Transferring any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to the Medical Research Facility. The written agreement shall constitute a business record. *See* Rule M 901 – Business Records Required. The written agreement shall include the following information:

1. The identity of the Medical Research Facility;

2. The quantity of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product that will be Transferred to the Medical Research Facility;

3. An affirmation by the Medical Research Facility that it (a) has received approval and funding from the State Board of Health for the research to be conducted on the marijuana; (b) remains authorized to receive the quantity of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product that will be Transferred to the Medical Research Facility; and (c) will destroy all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product that will be Transferred to the Medical Research Facility, following completion of research activities as required by subsection 25-1.5-106.5(5)(b), C.R.S.;

4. An affirmation by the Licensee that the Medical Research Facility has provided it with written proof of the State Board of Health's approval and funding of the Medical Research Facility's research; and

5. The date(s) upon which Transfer of the Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product will occur.

C. State Board of Health Approval. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall not Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product unless and until the State Board of Health approves and funds the Medical Research Facility's research pursuant to section 25-1.5-106.5, C.R.S.

1. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall not Transfer any Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product until the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer receives written proof of the State Board of Health's approval and funding of the Medical Research Facility's research. The written proof of the State Board of Health's approval and funding of the Medical Research Facility's research shall constitute a business record. *See* Rule M 901 – Business Records Required.

2. Transferring Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product to a Medical Research Facility before the Medical Research Facility receives approval and funding from the State Board of Health shall be considered a violation affecting public safety.

D. Inventory Tracking Requirements. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall track all Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product in the Inventory Tracking System until it is delivered to a Medical Research Facility.

1. Transport Manifest. A Licensee shall not deliver or permit the delivery of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product unless a manifest is generated from the Inventory Tracking System. *See* Rule M 801(C) Transport: All Medical Marijuana Businesses.

2. Complete Manifest. A Licensee shall not relinquish possession or control of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product to a Medical Research Facility until a natural person authorized by the Medical Research Facility acknowledges receipt of the Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Products by signing the transport manifest. *See* Rule M 801(I).

3. No Inventory Tracking Following Delivery. Once Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product has been Transferred by a Licensee to a Medical Research Facility, no further inventory tracking is required.

4. Licensee Delivery Responsibility. The originating Licensee is responsible for confirming delivery of the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product in the Inventory Tracking System. *See* Rule M 801(I).

E. Packaging, Labeling, and Testing. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that Transfers Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product to a Medical Research Facility shall package, label, and test all Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Products in conformance with these rules, prior to Transferring the Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product. *See* M

1000-1 Series – Labeling, Packaging, and Product Safety; M 1500 Series – Medical Marijuana Testing Program.

F. Business Records. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that Transfers Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product to a Medical Research Facility shall keep all documents concerning the relationship and Transfer of any Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product in accordance with Rules M 801 and M 901.

G. Quantity Limitations for Medical Research Facilities. A Medical Research Facility shall only use Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product for the medical research approved pursuant to section 25-1.5-106.5, C.R.S. A Medical Research Facility shall not possess at any time a quantity of Transferred Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product greater than the quantity approved by the research grant awarded to the Medical Research Facility by the State Board of Health. In no event shall the Medical Research Facility possess at any given time more than (i) 12 Medical Marijuana plants and (ii) four pounds of Medical Marijuana or its equivalency in Medical Marijuana Concentrate (512 grams) or Medical Marijuana-Infused Product (5,120 Medical Marijuana-Infused Products).

H. Colorado Department of Public Health and Environment and State Board of Health Administration. The Colorado Department of Public Health and Environment is responsible for the administration of grants to Medical Research Facilities pursuant to section 25-1.5-106.5(2), C.R.S. The Colorado Department of Public Health and Environment, through the Scientific Advisory council, has the authority to review and make recommendations regarding research grant proposals. The State Board of Health has the authority to approve or deny research grant proposals pursuant to section 25-1.5-106.5, C.R.S.

I. Disposal of Medical Marijuana. A Medical Research Facility shall destroy all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product following completion of research activities as required by subsection 25-1.5-106.5(5)(b), C.R.S.

J. No Transfer to Licensees. Under no circumstance may a Licensee receive or obtain for any purposes Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from a Medical Research Facility.

Basis and Purpose - M 1802

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b) and 12-43.3-202(1)(h)(II), C.R.S. The purpose of this rule is to establish requirements associated with the Transfer of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product to Pesticide Manufacturers, including requirements for the possession and disposition of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product by Pesticide Manufacturers.

M 1802 – Pesticide Manufacturers

A. Transfers to Pesticide Manufacturers. An Optional Premises Cultivation Operation may Transfer Medical Marijuana and Medical Marijuana Concentrate to a Pesticide Manufacturer solely for the purpose of conducting research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Medical Marijuana. *See also* Rule M 501. A Medical Marijuana-Infused Products Manufacturer may Transfer Medical Marijuana-Infused Product and Medical Marijuana Concentrate to a Pesticide Manufacturer solely for the purpose of research to establish safe and effective protocols, including but not limited to

establishing efficacy and toxicity, for the use of Pesticides on Medical Marijuana. *See also* Rule M 601.

B. Written Documentation Required. A Licensee shall require, and shall not Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product prior to receiving, written proof under oath, as evidenced by an affidavit entered into by an authorized person on behalf of the Pesticide Manufacturer, affirming that the Pesticide Manufacturer meets the requirements set forth in subparagraph (C)(4) of this Rule. This documentation shall constitute a business record under Rule M 901- Business Records Required.

C. Agreement with Pesticide Manufacturer. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that Transfers Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Pesticide Manufacturer shall enter into a written agreement with the Pesticide Manufacturer prior to Transferring any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to the Pesticide Manufacturer. The written agreement, which shall constitute a business record under Rule M 901, shall include:

1. The identity of the Pesticide Manufacturer;

2. The quantity of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product that will be Transferred to the Pesticide Manufacturer;

3. The date(s) upon which Transfer of the Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product will occur;

4. An affirmation by the Pesticide Manufacturer that it:

   i. Has an establishment number with the U.S. Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq*.;

   ii. Is authorized to do business in Colorado;

   iii. Is in possession of a physical location in the State of Colorado where its research activities will occur;

   iv. Has applied for and received any necessary license, registration, certification, or permit from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 *et seq.,* C.R.S. and/or the Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S.;

   v. Remains authorized to receive the quantity of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product that will be Transferred to the Pesticide Manufacturer; and

   vi. Will only use the Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product for the purpose of conducting research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Medical Marijuana; and,

5. An affirmation by the Licensee that it has received written proof the Pesticide Manufacturer meets the requirements set forth in subparagraph (C)(4) of this rule.

D. Inventory Tracking Requirements. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall track all Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product in the Inventory Tracking System until it is delivered to a Pesticide Manufacturer.

1. Transport Manifest. A Licensee shall not deliver or permit the delivery of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product unless a manifest is generated from the Inventory Tracking System.

2. Complete Manifest. A Licensee shall not relinquish possession or control of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Pesticide Manufacturer until a natural person authorized by the Pesticide Manufacturer acknowledges receipt of the Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product by signing the transport manifest.

3. No Inventory Tracking Following Delivery. Once Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product has been Transferred by a Licensee to a Pesticide Manufacturer, no further inventory tracking is required.

4. Licensee Delivery Responsibility. The originating Licensee is responsible for confirming delivery of all Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product in the Inventory Tracking System.

E. Packaging, Labeling, and Testing. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that Transfers Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product to a Pesticide Manufacturer shall package, label, and test all Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Products in conformance with these rules, prior to Transferring the Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product. *See* M 1000-1 Series – Labeling, Packaging, and Product Safety; M 1500 Series – Medical Marijuana Testing Program.

F. Business Records. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that Transfers Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Pesticide Manufacturer shall keep all documents concerning the relationship and Transfer of any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product in accordance with Rules M 801 and 901.

G. Pesticide Manufacturer Authorized Activities. A Pesticide Manufacturer is only authorized to possess Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product in order to conduct research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Medical Marijuana.

H. Quantity Limitations for Pesticide Manufacturer. In no event shall the Pesticide Manufacturer possess at any given time more than (i) 12 Medical Marijuana plants and (ii) four pounds of Medical Marijuana or its equivalency in Medical Marijuana Concentrate (512 grams) or Medical Marijuana-Infused Product (5,120 Medical Marijuana-Infused Products).

I. Disposition of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. A Pesticide Manufacturer shall destroy all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product following completion of research activities.

1. A Pesticide Manufacturer shall destroy Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product in conformance with Rule M 307 – Waste Disposal.

2. A Pesticide Manufacturer shall document the destruction of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product, which documentation shall include:

   i. Whether the destroyed material was Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product;

   ii. The date of destruction;

   iii. The location of the destruction;

   iv. The manner in which the Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product was rendered unusable and Unrecognizable;

   v. The method of final disposition pursuant to Rule M 307(F); and

   vi. The identity(ies) and contact information of all Person(s) involved in the destruction.

3. A Pesticide Manufacturer shall keep all documentation regarding destruction of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Products for the current year and three preceding calendar years.

J. No Pesticide on Licensed Premises. Under no circumstance may a Pesticide Manufacturer apply Pesticide(s) for research purposes on the Licensed Premises of a Medical Marijuana Business.

1. Licensees Shall Not Permit Pesticide on Licensed Premises. Under no circumstance may a Licensee allow or permit the application of Pesticide(s) by a Pesticide Manufacturer for research purposes on the Licensed Premises of a Medical Marijuana Business.

2. Violation Affecting Public Safety. A violation of this prohibition shall be considered a violation affecting public safety.

K. No Human or Animal Subjects. Under no circumstance shall a Pesticide Manufacturer receiving Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product from a Licensee engage in research involving human subjects. Additionally, under no circumstance shall a Pesticide Manufacturer receiving Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product from a Licensee engage in research involving animal subjects, as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g).

1. Licensees Shall Not Permit Human or Animal Subject Research. If a Licensee knows or reasonably should know that a Pesticide Manufacturer intends to engage in or has engaged in marijuana-related research involving human and/or animal subjects, the Licensee shall not Transfer any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to the Pesticide Manufacturer.

2. Violation Affecting Public Safety. A violation of this prohibition shall be considered a violation affecting public safety.

L. No Transfer to Licensees. Under no circumstance may a Licensee receive or obtain for any purposes Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from a Pesticide Manufacturer.

M 1900 Series –Licensed Research Businesses

Basis and Purpose - M 1901

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), 12-43.3-405(1), and 12-43.3-408, C.R.S. The purpose of this rule is to establish that it is unlawful for Licensed Research Businesses to exercise any privilege other than those granted by the State Licensing Authority. The purpose of this rule also is to clarify the distinct privileges granted to Marijuana Research and Development Facilities and Marijuana Research and Development Cultivations.

M 1901 – Licensed Research Businesses: License Privileges

A. Privileges Applicable to any Licensed Research Business.

1. Privileges Granted. A Licensed Research Business shall only exercise those privileges granted to it by the State Licensing Authority.

2. Licensed Premises. A Licensed Research Business may share a Licensed Premises only with a commonly-owned Medical Marijuana Testing Facility.

i. If a Licensed Research Business shares its Licensed Premises with a commonly-owned Medical Marijuana Testing Facility, the Licensees shall physically segregate all Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product used for research purposes in order to prevent contamination or any other effect on Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product submitted to the Medical Marijuana Testing Facility for testing.

3. Authorized Sources of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. A Licensed Research Business may receive or obtain Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product from only the following sources:

i. An Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer may Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Licensed Research Business.

ii. Marijuana Research and Development Cultivations. A Marijuana Research and Development Cultivation may Transfer Medical Marijuana to other Licensed Research Businesses.

B. Privileges Applicable to Marijuana Research and Development Cultivations.

1. Cultivation of Marijuana Authorized. A Marijuana Research and Development Cultivation may grow, cultivate, possess, and Transfer Medical Marijuana for use in research only.

2. Production of Marijuana Concentrate. A Marijuana Research and Development Cultivation and an Optional Premises Cultivation Operation are subject to the same restrictions concerning Medical Marijuana Concentrate production. Therefore, a Licensed Research Business may produce Medical Marijuana Concentrate only as allowed by, and in conformance with, Rule M 506(A)-(B).

3. Authorized Marijuana Transport. A Marijuana Research and Development Cultivation is authorized to utilize a licensed Medical Marijuana Transporter for transportation of Medical Marijuana to other Licensed Research Businesses so long as the place where

transportation orders are taken and delivered is a Licensed Research Business. Nothing in this rule prevents a Marijuana Research and Development Cultivation from transporting its own Medical Marijuana to other Licensed Research Businesses.

Basis and Purpose - M 1902

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), 12-43.3-310(7), 12-43.3-405(1), and 12-43.3-408, C.R.S. The purpose of this rule is to clarify those acts that are prohibited, or limited in some fashion, by a Licensed Research Business.

M 1902 – Licensed Research Businesses: General Limitations or Prohibited Acts

A. Restrictions Applicable to Any Licensed Research Business.

1. Packaging and Labeling Standards Required. A Licensed Research Business is prohibited from Transferring to a Licensee or any other Person Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that is not packaged and labeled in accordance with these rules. *See* Rule M 1000-1 Series – Labeling, Packaging, and Product Safety.

    i. Unless the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product was subject to contaminant testing required by the Medical Marijuana Code and these rules, a Licensed Research Business shall disclose to any individual Person receiving Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product as part of an approved Research Project that the Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product has not been subject to mandatory contaminant testing.

2. Transfers to Individuals. A Licensed Research Business is prohibited from Transferring Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to any individual, unless as part of an approved Research Project.

3. Consumption Prohibited. A Licensed Research Business shall not permit the consumption of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product on its Licensed Premises, unless as part of an approved Research Project and the Licensed Research Business does not share a Licensed Premises with a Medical Marijuana Testing Facility.

4. Transporter Restrictions. A Licensed Research Business shall not sell or give away Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Transporter, and shall not buy or receive complimentary Medical Marijuana, Medical Marijuana Concentrate, or Medical-Marijuana Infused Product from a Medical Marijuana Transporter.

5. Worker Health and Safety. A Licensed Research Business shall comply with all applicable federal, state, and local laws regarding worker health and safety.

6. Performance Incentives. A Licensed Research Business may not use performance incentives to compensate its employees, agents, or contractors who will conduct research, development, or testing.

7. Licensure and Research Projects. A Licensed Research Business shall not engage in any research activities until the State Licensing Authority or its delegate approves both

(1) its business license application, pursuant to Rule M 201, and (2) one or more Research Project(s), pursuant to Rule M 1904.

i. A Licensed Research Business may submit its business license application prior to or in conjunction with its Research Project application. Except that the Licensed Research Business may not engage in any research activities except in conjunction with an approved Research Project.

ii. If a Licensed Research Business's license expires or is suspended or revoked, the Licensee shall immediately cease all activities associated with the privileges of licensure, including but not limited to research.

B. Restrictions Applicable to Marijuana Research and Development Cultivations.

1. Transfer Restriction. A Marijuana Research and Development Cultivation may only Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Licensed Research Business, a Medical Marijuana Testing Facility for testing, or to any individual person as part of an approved Research Project.

C. Restrictions Applicable to Marijuana Research and Development Facilities.

1. Transfer Restriction. A Marijuana Research and Development Facility may only Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to an individual person as part of an approved Research Project or to a Medical Marijuana Testing Facility for testing.

Basis and Purpose - M 1903

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), and 12-43.3-202(2)(a)(XXII), and 12-43.3-408, C.R.S. The purpose of this rule is to require all Licensed Research Businesses to track all inventory from the point it is Propagated or received to the point when it is destroyed, used in a Research Project, or, if permitted, Transferred to another Licensed Research Business or a Medical Marijuana Testing Facility. The purpose of this rule is also to eliminate diversion of Medical Marijuana.

M 1903 – Licensed Research Businesses: Inventory Tracking

A. Minimum Tracking Requirement. A Licensed Research Business must use the Inventory Tracking System to ensure its inventories are identified and tracked from the point Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product is propagated or received to the point when it is destroyed, used in a Research Project, or, if permitted, Transferred to another Licensed Research Business or a Medical Marijuana Testing Facility. *See also* Rule M 309 - Medical Marijuana Business: Inventory Tracking System. A Licensed Research Business must have the ability to reconcile its inventory records generated from the Inventory Tracking System with the associated transaction history and sale receipts or other Transfer documentation. *See also* Rule M 901 – Business Records Required.

1. A Licensed Research Business is prohibited from accepting any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product without receiving a valid transport manifest generated from the Inventory Tracking System.

2. A Licensed Research Business must immediately input all Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product delivered to its Licensed Premises and account for all RFID tags into the Inventory Tracking System at the time of delivery.

3. A Licensed Research Business must reconcile its transaction history and on-hand Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product to the Inventory Tracking System at the close of business each day.

Basis and Purpose - M 1904

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI),12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), and 12-43.3-408(3)(a), C.R.S. The purpose of this rule is to ensure that any research or development conducted by a Licensed Research Business shall be in furtherance of a Research Project approved by the Division. The purpose of this rule is also to establish the applicable requirements necessary for Licensed Research Businesses to seek and receive Division approval for all proposed Research Projects.

M 1904 – Licensed Research Businesses: Project Approval

A. Project Approval. Prior to engaging in any research activities, a Licensed Research Business shall obtain approval from the Division for a Research Project by submitting a Research Project proposal. Any research or development conducted by a Licensed Research Business shall be in furtherance of an approved Research Project.

1. General. A Licensed Research Business Applicant or Licensee shall seek approval of the Division by submitting its Research Project proposal on the current form supplied by the Division.

a. A Research Project proposal shall include a description of the Research Project's defined protocol, clearly articulated goal(s), defined methods and outputs, and a defined start and end date.

i. The description of the proposed Research Project proposal shall include the quantity of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product reasonably required to conduct the proposed Research Project, the total quantity of which is subject to approval by the Division as part an approved Research Project.

b. A Licensed Research Business Applicant or Licensee shall disclose all Persons who have, are, or will provide funding for the proposed Research Project. If any Person funding or intending to fund the proposed Research Project does not hold a license issued by the State Licensing Authority, and is neither a Direct Beneficial Interest Owner nor an Indirect Beneficial Interest Owner of the Licensed Research Business, then such Person must be reported as an Affiliated Interest. An Affiliated Interest may not exercise control and may not be positioned so as to enable the exercise of control over the Licensed Research Business.

c. A Licensed Research Business may enter into contracts or agreements with a public higher education research institution or another Licensed Research Business to conduct the proposed Research Project. A Licensed Research Business Applicant or Licensee shall disclose all contracts or agreements with a public higher education research institution or a Licensed Research Business.

i. If a Licensed Research Business enters into a contract or agreement to conduct a Research Project with a public higher education research institution, all research activities involving possession of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall occur at the Licensed Research Business's Licensed

Premises. Employees, agents, or contractors of the public higher education research institution may not work at or conduct research activities at the Licensed Research Business's Licensed Premises unless they hold an Occupational License issued by the State Licensing Authority.

d. A Licensed Research Business may submit additional Research Project proposals at any time during which its license is current and valid.

2. Private Research. Unless the proposed Research Project is being conducted in whole or in part by a Public Institution or with Public Money, the Licensed Research Business Applicant or Licensee shall obtain a review of its proposed Research Project by one or more independent reviewers. The Division, in its discretion, may require a Licensed Research Business Applicant or Licensee to nominate multiple independent reviewers. The Division must approve each nominated independent reviewer.

a. Fees and Costs. The Applicant or Licensee shall be solely responsible for any fees or costs associated with all aspects and all stages of the independent reviewer's services.

b. Qualifications of an Independent Reviewer. Each independent reviewer nominated by a Licensed Research Business Applicant or Licensee must be a qualified researcher within the field of study that relates to proposed Research Project.

i. The Division may consult with the Colorado Department of Public Health and Environment and/or the Colorado Department of Agriculture in reviewing whether a nominated independent reviewer is qualified to review the Licensed Research Business's Research Project.

ii. The Division, in its discretion, may require a nominated independent reviewer or the Licensed Research Business to provide additional information or analysis that the Division deems pertinent to its review of whether to approve the Licensee's nomination of the independent reviewer.

c. Conflicts of Interest. A Licensed Research Business Applicant or Licensee must disclose all pre-existing financial, employment, business, or personal relationships between the Licensed Research Business or any of its Associated Key Licensees and each independent reviewer. In determining whether to approve an independent reviewer, the Division may consider whether a pre-existing relationship exists that could affect the independent reviewer's independence or appearance of independence.

d. Independent Reviewer Approval Required. If a Licensed Research Business Applicant or Licensee nominates an independent reviewer who is not approved by the Division, the State Licensing Authority may deny a Research Project on that ground unless and until the Licensed Research Business Applicant or Licensee nominates another independent reviewer who is approved by the Division.

e. Independent Reviewer Report. After an independent reviewer has been approved by the Division, the Licensed Research Business Applicant or Licensee shall submit a report by the independent reviewer to the Division as part of its

Research Project proposal. The independent reviewer's report shall address the following criteria as described in the Research Project's description:

i. The identity of the independent reviewer and his/her employer;

ii. Any compensation paid by the Licensed Research Business Applicant or Licensee for the review and report;

iii. A description of the review conducted by the independent reviewer, including but not limited to an identification of all documents that were reviewed;

iv. An analysis by the independent reviewer as to whether the proposed Research Project constitutes a type of approved research pursuant to Rule M 1905(A) and the reason(s) supporting the reviewer's analysis;

v. An assessment of the total quantity of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product reasonably required to conduct the proposed Research Project;

vi. An assessment of whether the proposed Research Project presents any type of danger to the public health and/or safety, and/or whether the proposed Research Project presents any health or safety risks;

vii. An assessment of whether the proposed Research Project has a strong scientific basis, appropriate study design, and technically sound scientific methodology;

viii. An assessment of whether the Licensed Research Business Applicant or Licensee is qualified to perform the proposed Research Project, including whether the Licensed Research Business Applicant or Licensee's employees are qualified to perform the proposed Research Project;

ix. An assessment of whether the Licensed Research Business Applicant or Licensee has the appropriate resources and protocols to conduct the proposed Research Project;

x. An assessment of whether the Licensed Research Business Applicant or Licensee has the appropriate personnel, expertise, facilities, infrastructure, funding, and other human, animal, or other approvals in place to successfully conduct the Research Project, including but not limited to the requirements in Rule M 1905(C) and (D);

xi. The following certification by the independent reviewer: "I hereby certify and affirm that I do not have any financial, employment, business, or personal relationship with [INSERT LICENSED RESEARCH BUSINESS NAME] ("Licensee") that would influence or affect my review of the Licensee's proposed Research Project activity. Other than the fees disclosed herein, neither the Licensee nor any other person has given me anything of value or made any promises to me that would influence or affect my review of the Licensee's proposed research activity. I further certify and affirm that this report was drafted by me, and that the information, analysis, and conclusions herein represent solely my work and conclusions."; and

xii. The signature of the independent reviewer.

f. The Licensed Research Business shall maintain copies of all documents and correspondence sent to or from the independent reviewer. *See* Rule M 901 – Business Records Required.

g. The Division, in its discretion, may require the independent reviewer and/or the Licensed Research Business Applicant or Licensee to provide additional information or analysis that the Division deems pertinent to its review of the Applicant or Licensee's Research Project proposal.

h. The State Licensing Authority may decline to approve a Research Project proposal if an independent reviewer or the Division through further investigation concludes that:

i. The description of the Research Project does not meet the requirements of section 12-43.3-408, C.R.S., and these rules;

ii. The proposed Research Project presents a danger to the public health and/or safety, and/or the research to be conducted pursuant to the Research Project presents any health or safety risks;

iii. The proposed Research Project lacks scientific value or validity;

iv. The Licensed Research Business Applicant or Licensee is not qualified to perform the proposed research;

v. The Licensed Research Business Applicant or Licensee does not have the appropriate resources and/or protocols to conduct the proposed research;

vi. The Licensed Research Business Applicant or Licensee lacks the appropriate personnel, expertise, facilities, infrastructure, funding, or human, animal, or other approvals in place to successfully conduct the Research Project, including but not limited to the requirements in Rule M 1905(C) and (D);

vii. The independent reviewer(s) cannot meet the certification requirements in this rule; or

viii The Licensed Research Business Applicant or Licensee or the proposed Research Project is otherwise not in compliance with the Medical Code or these rules.

3. Projects with Public Institutions or Money. If a Licensed Research Business Applicant or Licensee's proposed Research Project will be conducted in whole or in part with a Public Institution or Public Money, the Division shall refer the Licensee's Research Project proposal to the Scientific Advisory Council established by section 25-1.5-106.5(3), C.R.S., for review.

a. The Licensed Research Business Applicant or Licensee shall supply the Scientific Advisory Council with any information and/or documents requested by the Scientific Advisory Council within the deadline imposed by the Scientific Advisory Council. A Licensed Research Business Applicant or Licensee's failure to supply information and/or documents requested by the Scientific Advisory

Council within the deadline set by the Scientific Advisory Council shall be grounds for denial of the Research Project proposal.

b. The Scientific Advisory Council shall review the proposed Research Project to ensure that the proposed Research Project meets the requirements of Rule M 1905(A).

c. The Scientific Advisory Council shall also assess the adequacy of the following:

i. The proposed Research Project's quality, study design, value, or impact;

ii. Whether the Licensed Research Business Applicant or Licensee has the appropriate personnel, expertise, facilities, infrastructure, funding, and human, animal, or other approvals in place to successfully conduct the Research Project, including but not limited to the requirements in Rule M 1905(C) and (D); and

iii. Whether the amount of Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product the Licensed Research Business Applicant or Licensee proposes to grow or possess is consistent with the proposed Research Project's scope and goals.

d. The Scientific Advisory Council shall communicate the results of its review of the proposed Research Project to the Division. If the Scientific Advisory Council determines that the requirements of either Paragraph (b) or (c) of this Rule are not satisfied, then the proposed Research Project shall be denied.

e. The Licensed Research Business shall maintain copies of all documents and correspondence sent to or from the Scientific Advisory Council. *See* Rule M 901 – Business Records Required.

Basis and Purpose - M 1905

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), 12-43.3-405(1), and 12-43.3-408(2), C.R.S. The purpose of this rule to establish the limited research purposes authorized for Licensed Researched Businesses. The purpose of this rule is also to establish additional requirements for Research Projects involving human subjects and animal subjects, as well as restrictions on the use of Pesticides. The rule also establishes reporting requirements and explains when the State Licensing Authority may require a Licensed Research Business to undergo an audit of its research activities.

M 1905 – Licensed Research Businesses: Authorized Research Activities

A. Authorized Research. A Licensed Research Business is authorized to engage in the following research at its Licensed Premises:

1. Chemical Potency and Composition Levels.

2. Clinical Investigations of Marijuana-Derived Products.

3. Efficacy and Safety of Administering Marijuana as Part of Medical Treatment.

4. Genomic Research.

5. Horticultural Research.

6. Agricultural Research.

7. Marijuana-Affiliated Products or Systems. A marijuana-affiliated product or system includes products or systems such as marijuana delivery systems and cultivation or processing equipment.

B. Pesticide Research. A Licensed Research Business shall not engage in any research activities involving Pesticides unless the Licensed Research Business has applied for and received any necessary license, registration, certification, or permit from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 *et seq.,* C.R.S., and/or the Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S.

1. A Licensed Research Business engaged in research activities involving Pesticide shall at all times comply with the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S., Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S., and all rules promulgated pursuant thereto.

C. Research Involving Human Subjects. A Licensed Research Business shall not conduct any research involving human subjects unless all aspects of its proposed Research Project have been reviewed and approved by an Institutional Review Board that is registered and in good standing with Office for Human Research Protections, U.S. Department of Health and Human Services.

1. A Licensed Research Business shall include proof of approval and ongoing oversight and review by an Institutional Review Board as part of its Research Project proposal. A Research Project may be approved conditioned upon subsequent Institutional Review Board approval. A Licensee shall not engage in any Research Project involving human subjects until it receives approval by the Institutional Review Board and its Research Project is approved. A Licensed Research Business conducting research involving human subjects shall also comply with any ongoing monitoring required by the Institutional Review Board.

2. A Licensed Research Business conducting research involving human subjects shall at all times comply with the U.S. Department of Health and Human Services' requirements for protection of human research subjects, including additional safeguards necessary for vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, 45 C.F.R. part 46, and all other relevant federal and/or state laws and regulations regarding research on human subjects, as well as all prevailing ethical standards and requirements for research involving human subjects.

3. A Licensed Research Business conducting research involving human subjects shall obtain informed consent from any individual participating in such research prior to the individual's participation in the research. A Licensed Research Business shall comply with U.S. Food and Drug Administration requirements for informed consent and additional safeguards for children in clinical investigations, 21 C.F.R. part 50, as part of approval and ongoing oversight and review by an Institutional Review Board.

D. Research Involving Animal Subjects. A Licensed Research Business shall not conduct any research involving animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g) unless the Licensed Research Business is registered with the U.S. Department of Agricultural pursuant to the Animal Welfare Act, 7 U.S.C. §§ 2131 *et seq.*

1. A Licensed Research Business shall include proof of its current registration with the U.S. Department of Agriculture as part of its Research Project proposal. Failure to be

registered with the U.S. Department of Agriculture shall be grounds for denial of Research Project proposal involving animal subjects.

2. A Licensed Research Business shall at all times treat animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g) involved in research humanely and consistent with all relevant federal and/or state laws and regulations, as well as all prevailing ethical standards and requirements for research on such animals.

E. Research Involving Testing of Marijuana. A Licensed Research Business may only engage in research regarding the testing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product if the following criteria are met:

1. Testing Qualifications. A Licensed Research Business must meet one of the following standards:

a. The Licensed Research Business also holds a Medical Marijuana Testing Facility license and has been certified pursuant to Rule M 703;

b. The Licensed Research Business is accredited to the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO 17025 standard; or

c. The Licensed Research Business is part of an institution of higher education whose protocols have been approved by the Colorado Department of Public Health and Environment.

2. A Licensed Research Business proposing to engage in research regarding the testing Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall include in its Research Project proposal documentation establishing its testing qualification pursuant to Paragraph (E)(1) of this Rule. *See* Rule M 1904 – Licensed Research Businesses: Project Approval.

F. No Transfers of Marijuana Used in Research. A Licensed Research Business shall not Transfer to any Person any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that has been used by the Licensee for research. Unless otherwise provided by the State Licensing Authority, a Licensed Research Business shall at the conclusion of its research destroy all remaining Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product subject to the Licensed Research Business's approved Research Project. Unless otherwise provided, a Research Project will be deemed concluded on its defined end date as provided in the Licensed Research Business's Research Project proposal that was submitted to and approved by the Division. The Licensed Research Business shall ensure destruction of such remaining Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana-Infused Product is destroyed in conformance with Rule M 307.

G. Periodic Reporting. A Licensed Research Business shall submit to the Division a report regarding the status of approved Research Projects every 6 months following the Division's approval of its Research Project.

1. The periodic reports shall address the Licensed Research Business's compliance and progress with its approved Research Project.

2. The periodic reports shall include any protocol changes or reported protocol deviations, as well as enrollment numbers and adverse events for studies involving human subjects.

3. If the Licensed Research Business is conducting its Research Project in whole or in part with a Public Institution or Public Money, the Division shall submit the Licensed Research Business's periodic reports to the Scientific Advisory Council for review.

4. If an adverse event occurs, the Licensed Research Business shall immediately notify the Division of the adverse event on the form prepared by the Division.

H. Suspension or Revocation of Project Approval. Research Project approval is subject to revocation or suspension if the Licensed Research Business's research has materially diverged from the Licensed Research Business's approved Research Project, violates the Medical Marijuana Code or the rules promulgated thereto, or presents a risk to public health and safety. *See* Rule M 1300 Series – Discipline.

I. Reporting of Research Results. A Licensed Research Business shall supply the Division with copies of all final reports, findings, or documentation regarding the outcomes of approved Research Projects.

J. Independent Research Audit. The State Licensing Authority in its discretion may at any time require that a Licensed Research Business undergo an audit of its research activities.

1. Circumstances Justifying Independent Research Audit. The following is a non-exhaustive list of examples that may justify an independent research audit:

a. The Division has reasonable grounds to believe that the Licensed Research Business is in violation of one or more of the requirements set forth in these rules or other applicable statutes or regulations;

b. The Division has reasonable grounds to believe that the Licensed Research Business's research activities present a danger to the public health and/or safety; or

c. The Division has reasonable grounds to believe that the Licensed Research Business has been or is engaged in research activities that have not received prior Division approval.

2. Selection of An Independent Consultant. The Division and the Licensed Research Business may attempt to mutually agree upon the selection of an independent consultant to perform a research audit. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

3. Costs. The Licensed Research Business subject to an independent research audit will be responsible for all costs associated with the independent research audit, including but not limited to the auditor's fees.

4. Compliance Required. A Licensed Research Business must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent research audit in conformance with this Rule.

K. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose - M 1906

The statutory authority for this rule includes but is not limited to sections 12-43.3-202 and 12-43.3-408, C.R.S. The purpose of this rule is to establish minimum health and safety regulation for Licensed

Research Businesses. It sets forth general standards and basic sanitary requirements for Licensed Research Businesses. It covers the Licensed Premises as well as the individuals handling Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product. The rule prohibits Licensed Research Business from treating or otherwise adulterating Medical Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell. This rule also authorizes the State Licensing Authority to require an independent consultant to conduct an independent health and sanitary audit of an Licensed Research Businesses. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Licensed Research Business's refusal to cooperate or pay for the audit. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Licensed Research Businesses.

M 1906 – Licensed Research Businesses: Health and Safety Regulations

A. Local Safety Inspections. A Licensed Research Business may be subject to inspection of its Licensed Premises by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local jurisdiction restrictions related to Medical Marijuana Businesses or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

B. General Sanitary Requirements. A Licensed Research Business shall take all reasonable measures and precautions to ensure the following:

1. That any Person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in contamination until the condition is corrected;

2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

3. That all Persons working in direct contact with Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:

    a. Maintaining adequate personal cleanliness;

    b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated; and

    c. Refraining from having direct contact with Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

4. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of

contamination in areas where Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Product are exposed;

5. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;

6. That there is adequate lighting in all areas where Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product are stored, where research and development activities are conducted, and where equipment or utensils are cleaned;

7. That the Licensed Research Business provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

8. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;

9. That toxic cleaning compounds, sanitizing agents, and solvents shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product, unless as part of an approved Research Project, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. All Pesticide must be stored and disposed of in accordance with the information provided on the product's label;

10. That all contact surfaces, including utensils and equipment used for the preparation and research of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used by a Licensed Research Business and used in accordance with labeled instructions;

11. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs. Reclaimed water may also be used only for the cultivation of Medical Marijuana, and subject to approval of the Water Quality Control Division of the Colorado Department of Public Health and Environment and the local water provider;

12. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the Licensed Premises and that plumbing shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable, reclaimed water, and waste water lines;

13. That all operations in the receiving, inspecting, transporting, segregating, preparing, packaging, researching, and storing of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles;

14. That each Licensed Research Business shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and

15. That Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms, unless as part of an approved Research Project.

C. Pesticide Application. Unless as part of an approved Research Project, a Licensed Research Business may only use Pesticide in accordance with the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S., the Pesticide Applicators' Act," sections 35-10-101 *et seq.*, C.R.S., and all other applicable federal, state, and local laws, statutes, rules and regulations. *See also* Rule M 1905(B). This includes, but shall not be limited to, the prohibition on detaching, altering, defacing, or destroying, in whole or in part, any label on any Pesticide.

D. Application of Other Agricultural Chemicals. Unless as part of an approved Research Project, a Licensed Research Business may only use agricultural chemicals, other than Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules and regulations.

E. Required Documentation.

1. Marijuana Research and Development Cultivation.

i. Standard Operating Procedures. A Marijuana Research and Development Cultivation must establish written standard operating procedures for the cultivation of Medical Marijuana. The standard operating procedures must at least include when, and the manner in which, all Pesticide and other agricultural chemicals are to be applied during its cultivation process. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Marijuana Research and Development Cultivation.

ii. Material Change. If a Marijuana Research and Development Cultivation makes a Material Change to its cultivation procedures, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

2. Safety Data Sheet. A Licensed Research Business must obtain a safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. A Licensed Research Business must maintain a current copy of the safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.

3. Labels of Pesticide and Other Agricultural Chemicals. A Licensed Research Business must have the original label or a copy thereof at its Licensed Premises for all Pesticide and other agricultural chemicals used on its Licensed Premises.

4. Pesticide Application Documentation. A Licensed Research Business that applies any Pesticide or other agricultural chemical to any portion of a Medical Marijuana plant, water, or feed used during cultivation or generally within the Licensed Premises must document, and maintain a record on its Licensed Premises of, the following information:

a. The name, signature, and Occupational License number of the individual who applied the Pesticide or other agricultural chemical;

b. Applicator license, certification number or permit number, if the applicator is licensed, certified or permitted through the Department of Agriculture in accordance with the Colorado Pesticides Applicators' Act, sections 35-10-101 *et seq.*, C.R.S.;

c. The date and time of the application;

d. The EPA registration number of the Pesticide or CAS number of any other agricultural chemical(s) applied;

e. Each of the active ingredients of the Pesticide or other agricultural chemical(s) applied;

f. Brand name and product name of the Pesticide or other agricultural chemical(s) applied;

g. The restricted entry interval from the product label of any Pesticide or other agricultural chemical(s) applied;

h. The RFID tag number of the Medical Marijuana plant(s) that the Pesticide or other agricultural chemical(s) was applied to or if applied to all plants throughout the Licensed Premises, a statement to that effect; and

i. The total amount of each Pesticide or other agricultural chemical applied.

F. Prohibited Chemicals. The following chemicals shall not be used on a Licensed Research Business's Licensed Premises, unless as part of an approved Research Project. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this rule, unless as part of an approved Research Project. Prohibited chemicals are:

ALDRIN

309-00-2

ARSENIC OXIDE (3)

1327-53-3

ASBESTOS (FRIABLE)

1332-21-4

AZODRIN

6923-22-4

1,4-BENZOQUINONE, 2,3,5,6-TETRACHLORO-

118-75-2

BINAPACRYL

485-31-4

2,3,4,5-BIS (2-BUTENYLENE) TETRAHYDROFURFURAL

126-15-8

BROMOXYNIL BUTYRATE

EDF-186

CADMIUM COMPOUNDS

CAE750

CALCIUM ARSENATE [2ASH3O4.2CA]

7778-44-1

CAMPHECHLOR

8001-35-2

CAPTAFOL

2425-06-1

CARBOFURAN

1563-66-2

CARBON TETRACHLORIDE

56-23-5

CHLORDANE

57-74-9

CHLORDECONE (KEPONE)

143-50-0

CHLORDIMEFORM

6164-98-3

CHLOROBENZILATE

510-15-6

CHLOROMETHOXYPROPYLMERCURIC ACETATE [CPMA] EDF-

183

COPPER ARSENATE

10103-61-4

2,4-D, ISOOCTYL ESTER

25168-26-7

DAMINOZIDE

1596-84-5

DDD

72-54-8

DDT

50-29-3

DIMETHYLSULFOXIDE (DMSO)

67-68-5

DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS] EDF-

187

1,2-DIBROMO-3-CHLOROPROPANE (DBCP)

96-12-8

1,2-DIBROMOETHANE

106-93-4

1,2-DICHLOROETHANE

107-06-2

DIELDRIN

60-57-1

4,6-DINITRO-O-CRESOL

534-52-1

DINITROBUTYL PHENOL

88-85-7

ENDRIN

72-20-8

EPN

2104-64-5

ETHYLENE OXIDE

75-21-8

FLUOROACETAMIDE

640-19-7

GAMMA-LINDANE

58-89-9

HEPTACHLOR

76-44-8

HEXACHLOROBENZENE

118-74-1

1,2,3,4,5,6-HEXACHLOROCYCLOHEXANE (MIXTURE OF ISOMERS)

608-73-1

1,3-HEXANEDIOL, 2-ETHYL-

94-96-2

LEAD ARSENATE

7784-40-9

LEPTOPHOS

21609-90-5

MERCURY

7439-97-6

METHAMIDOPHOS

10265-92-6

METHYL PARATHION

298-00-0

MEVINPHOS

7786-34-7

MIREX

2385-85-5

NITROFEN

1836-75-5

OCTAMETHYLDIPHOSPHORAMIDE

152-16-9

PARATHION

56-38-2

PENTACHLOROPHENOL

87-86-5

PHENYLMERCURIC OLEATE [PMO]

EDF-185

PHOSPHAMIDON

13171-21-6

PYRIMINIL

53558-25-1

SAFROLE

94-59-7

SODIUM ARSENATE

13464-38-5

SODIUM ARSENITE

7784-46-5

2,4,5-T

93-76-5

TERPENE POLYCHLORINATES (STROBANE6)

8001-50-1

THALLIUM(I) SULFATE

7446-18-6

2,4,5-TP ACID (SILVEX)

93-72-1

TRIBUTYLTIN COMPOUNDS

EDF-184

2,4,5-TRICHLOROPHENOL

95-95-4

VINYL CHLORIDE

75-01-4

G. Adulterants. Unless as part of an approved Research Project, a Licensed Research Business may not treat or otherwise adulterate Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product with any chemical or other compound whatsoever to alter its color, appearance, weight or smell.

H. Independent Health and Sanitary Audit.

1. State Licensing Authority May Require a Health and Sanitary Audit.

a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Licensed Research Business to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Licensed Research Business is in compliance with the requirements set forth in this rule and other applicable public health or sanitary laws and regulations.

b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Licensed Research Business. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

c. The Licensed Research Business will be responsible for all costs associated with the independent health and sanitary audit.

2. When Independent Health and Sanitary Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:

a. A Licensed Research Business does not provide requested records related to the use of Pesticide or other agricultural chemicals during in the cultivation process;

b. The Division has reasonable grounds to believe that the Licensed Research Business is in violation of one or more of the requirements set forth in this Rule or other applicable public health or sanitary laws, rules, or regulations;

c. The Division has reasonable grounds to believe that the Licensed Research Business was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product; or

d. Multiple Harvest Batches or Production Batches produced by the Licensed Research Business failed contaminant testing.

3. Compliance Required. A Licensed Research Business must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this Rule.

I. Suspension of Operations.

1. If the State Licensing Authority has objective and reasonable grounds to believe and finds upon reasonable ascertainment of the underlying facts that the public health, safety, or welfare imperatively requires emergency action and incorporates such findings into its order, it may order summary suspension of the Licensed Research Business's license. *See* Rule M 1302 – Disciplinary Process: Summary Suspensions.

2. Prior to or following the issuance of such an order, the Licensed Research Business may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.

    i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. *See* Rule M 1302 – Disciplinary Process: Summary Suspensions.

    ii. If an agreement to suspend operations is reached, then the Licensed Research Business may continue to care for its inventory and conduct any necessary internal business operations but it may not Transfer Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to other Medical Marijuana Business's during the period of time specified in the agreement.

J. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose - M 1907

The statutory authority for this rule includes but is not limited to sections 12-43.3-202, 12-43.3-405, and 12-43.3-408, C.R.S. The purpose of this rule is to permit laboratory testing of Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana-Infused Products used by Licensed Research Businesses. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Licensed Research Businesses.

M 1907 – Licensed Research Businesses: Testing

A. Samples on Demand. Upon request of the Division, a Licensed Research Business shall submit a sufficient quantity of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing. The Division will notify the Licensed Research Business of the results of the analysis. *See* Rule M 309 – Medical Marijuana Business: Inventory Tracking System; Rule M 901 – Business Records Required.

B. Samples Provided for Testing. A Licensed Research Business may provide Samples of its Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing purposes. The Licensed Research Business shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.

Basis and Purpose - M 1908

The statutory authority for this rule includes but is not limited to sections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2)(a)(XXII), and 12-43.3-408, C.R.S. The purpose of this rule is to establish a Licensed Research Business may only possess an amount of Medical Marijuana, Medical Marijuana

Concentrate, or Medical Marijuana-Infused Product Medical Marijuana approved in conjunction with the Licensee's approved Research Projects. The purpose of this rule is also to establish additional Inventory Tracking and separation requirements for Medical Marijuana cultivated for Transfer by a Marijuana Research and Development Cultivation.

M 1908 – Licensed Research Businesses: Production Management and Possession Limits

A. Marijuana Authorized for Transfer. A Marijuana Research and Development Cultivation that is authorized to cultivate Medical Marijuana for Transfer to Licensed Research Businesses may not have more than 500 Medical Marijuana plants and 20 pounds of Medical Marijuana on its Licensed Premises at any given time, unless expressly approved by the Division as part of an approved Research Project.

1. A Marijuana Research and Development Cultivation Licensee shall indicate in the Inventory Tracking System whether Medical Marijuana is going to be used by the Licensee in an approved Research Project or Transferred to another Licensed Research Business. A Marijuana Research and Development Cultivation may cultivate Medical Marijuana prior to approval of a Research Project, except the Marijuana Research and Development Cultivation may only designate such Medical Marijuana as Medical Marijuana to be Transferred to other Licensed Research Businesses unless or until the Marijuana Research Development Cultivation has an approved Research Project. Upon approval of a Research Project, a Marijuana Research and Development Cultivation shall indicate in the Inventory Tracking System whether any such Medical Marijuana authorized for Transfer will be subject to the Marijuana Research and Development Cultivation's research pursuant to the approved Research Project.

B. Marijuana for Research. A Licensed Research Business shall only possess for research the amount of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product approved by the Division pursuant to each of the Licensee's approved Research Projects.

C. Separation of Marijuana Used in Research. A Marijuana Research and Development Cultivation shall physically separate all Medical Marijuana used in the Licensee's own approved Research Project(s) from Medical Marijuana to be Transferred to other Licensed Research Businesses for approved Research Projects.